

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité/ Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

MICRO-MEGA SA
12, rue du Tunnel
25000 BESANCON FRANCE

Catégorie du(des) dispositif(s) / Device(s) category

Dispositifs médicaux destinés à l'art dentaire et la chirurgie.

Medical devices for dental art and surgery.

Voir document complémentaire GMED / See GMED additional document

n° 37851

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600256 - P600975, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P600256 - P600975, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : May 12th, 2021 (included)

Valable jusqu'au / Expiry date : May 26th, 2024 (included)



On behalf of the President
Béatrice LYS
Technical Director

Ce document complémentaire GMED n° 37851 rev. 1 atteste de la validité du certificat CE n° 8881 rev. 28 au regard des informations listées ci-dessous.

This GMED additional document N° 37851 rev. 1 attests to the validity of CE certificate n° 8881 rev. 28 with regard to the information listed below.

Fabricant / Manufacturer:

MICRO-MEGA SA
12, rue du Tunnel
25000 BESANCON
FRANCE

Identification des dispositifs / Identification of devices

Version française :

Dispositifs médicaux destinés à l'art dentaire et la chirurgie.

Dentaire : Instruments canaux dentaires (stériles et non stériles) :

Lime endodontique Rotative / Reciproque, réutilisable

Porte-matériau d'obturation endodontique

Broche endodontique, dentée, usage unique

Broche endodontique, dentée, usage unique

Spreader endodontique Rotatif / Reciproque, stérile

Spreader endodontique Rotatif / Reciproque, non stérile

Lime endodontique Rotative / Reciproque, usage unique, non stérile

Instrument endodontique d'extraction

Lime endodontique Rotative / Reciproque, usage unique, stérile

Instrument endodontique sonique

Dentaire : Pièce à mains, contre-angles, moteurs.... :

Pièce à main, contre-angle dentaire

GMED 0459

GMED - 37851 rev. 1
Modifie le document n° 37851 rev. 0

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On behalf of the President
Béatrice LYS
Technical Director

Version anglaise :

Medical devices for dental art and surgery.

Dentistry : Root canal instruments (sterile or not sterile) :

Rotary/reciprocating endodontic file, reusable

Endodontic filling material carrier

Endodontic broach, serrated, reusable

Endodontic broach, serrated, single-use

Rotary/reciprocating endodontic spreader, sterile

Rotary/reciprocating endodontic spreader, non-sterile

Rotary/reciprocating endodontic file, single-use, non-sterile

Endodontic file retrieval loop

Rotary/reciprocating endodontic file, single-use, sterile

Sonic Endodontic broach

Dentistry : Hand-piece, contra-angle, motor ... :

Dental Handpiece / Contra-angle

Les produits couverts par ce certificat sont référencés sur la liste des produits authentifiée (19 pages) par GMED le 12 mai 2021.

The products covered by this certificate are listed on the devices's list authenticated (19 pages) by GMED on May 12, 2021.

Sites couverts et Activités / Locations and Activities

- **MICRO-MEGA SA – 12, rue du Tunnel - 25000 BESANCON – FRANCE**
Headquarter – Design, manufacturing and final control activities

GMED 0459

GMED - 37851 rev. 1

Modifie le document n° 37851 rev. 0



On behalf of the President
Béatrice LYS
Technical Director

Micro-Mega SA
12 rue du Tunnel
25000 BESANCON
France

GMED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits le 12 mai 2021

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed on May 12, 2021

COLTENE
MicroMega

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

Micro-Mega SA certifie que les produits suivants sont conformes à l'annexe I et VII de la directive 93/42 CEE relative aux dispositifs médicaux, en tenant compte de toutes les normes harmonisées européennes applicables et aux transpositions en droit national de chaque état et que son système d'assurance qualité, selon l'annexe II excluant le point 4 de la directive 93/42 CEE, est approuvé (Attestation CE n°8881 délivrée par l'organisme notifié GMED).

Micro-Mega SA certifies that the products listed below conform to annex I and VII of the Directive 93/42/EEC for medical devices, taking into account all applicable European harmonised standards and national laws for each state and that its full quality assurance system, according annex II excluding point 4 of the Directive 93/42/EEC, is approved (CE certificate n°8881 delivered by notified body GMED).

-	DISPOSITIFS MEDICAUX DESTINES A L'ART DENTAIRE ET A LA CHIRURGIE / MEDICAL DEVICES FOR DENTAL ART AND SURGERY			-	TECHNICAL
REFERENCE	FAMILY	DESIGNATION		CLASS	FILES
20147101	CMA GOLD	P6 CMA GOLD Asst L25 Classics	P6 MM GOLD Asst L25 Classics	Ila	6
20147102	CMA GOLD	P6 CMA GOLD Asst L21 Classics	P6 MM GOLD Asst L21 Classics	Ila	6
20147103	CMA GOLD	P6 CMA GOLD Asst L29 Classics	P6 MM GOLD Asst L29 Classics	Ila	6
20147110	CMA GOLD	P6 CMA GOLD CORONAL n25 10% L17 Classics	P6 CMA GOLD CORONAL n25 10% L17 Classics	Ila	6
20147115	CMA GOLD	P6 CMA GOLD MEDIAN n25 6% L21 Classics	P6 CMA GOLD MEDIAN n25 6% L21 Classics	Ila	6
20147116	CMA GOLD	P6 CMA GOLD MEDIAN n25 6% L25 Classics	P6 CMA GOLD MEDIAN n25 6% L25 Classics	Ila	6
20147120	CMA GOLD	P6 CMA GOLD APICAL1 n20 4% L21 Classics	P6 CMA GOLD APICAL1 n20 4% L21 Classics	Ila	6
20147121	CMA GOLD	P6 CMA GOLD APICAL1 n20 4% L25 Classics	P6 CMA GOLD APICAL1 n20 4% L25 Classics	Ila	6
20147122	CMA GOLD	P6 CMA GOLD APICAL1 n20 4% L29 Classics	P6 CMA GOLD APICAL1 n20 4% L29 Classics	Ila	6
20147125	CMA GOLD	P6 CMA GOLD APICAL2 n20 6% L21 Classics	P6 CMA GOLD APICAL2 n20 6% L21 Classics	Ila	6
20147126	CMA GOLD	P6 CMA GOLD APICAL2 n20 6% L25 Classics	P6 CMA GOLD APICAL2 n20 6% L25 Classics	Ila	6
20147127	CMA GOLD	P6 CMA GOLD APICAL2 n20 6% L29 Classics	P6 CMA GOLD APICAL2 n20 6% L29 Classics	Ila	6
20147131	CMA GOLD	P6 CMA GOLD APICAL3 n30 6% L25 Classics	P6 CMA GOLD APICAL3 n30 6% L25 Classics	Ila	6
20147136	CMA GOLD	P6 CMA GOLD APICAL4 n40 7% L25 Classics	P6 CMA GOLD APICAL4 n40 7% L25 Classics	Ila	6
20147001	CMA ROTARY FILE	MMC10-15/25 Coronal/17 Median/25 Apical1-2/25	MMC10-15/25 Coronal/17 Median/25 Apical1-2/25	Ila	6
20147002	CMA ROTARY FILE	MMC10-15/21 Coronal/17 Median/21 Apical1-2/21	MMC10-15/21 Coronal/17 Median/21 Apical1-2/21	Ila	6
20147003	CMA ROTARY FILE	MMC10-15/29 Coronal/17 Median/25 Apical1-2/29	MMC10-15/29 Coronal/17 Median/25 Apical1-2/29	Ila	6
20147010	CMA ROTARY FILE	P6 n25 10% L17 Classics	P6 n25 10% L17 Classics	Ila	6
20147015	CMA ROTARY FILE	P6 n25 6% L21 Classics	P6 n25 6% L21 Classics	Ila	6
20147016	CMA ROTARY FILE	P6 n25 6% L25 Classics	P6 n25 6% L25 Classics	Ila	6
20147020	CMA ROTARY FILE	P6 n20 4% L21 Classics	P6 n20 4% L21 Classics	Ila	6
20147021	CMA ROTARY FILE	P6 n20 4% L25 Classics	P6 n20 4% L25 Classics	Ila	6
20147022	CMA ROTARY FILE	P6 n20 4% L29 Classics	P6 n20 4% L29 Classics	Ila	6
20147025	CMA ROTARY FILE	P6 n20 6% L21 Classics	P6 n20 6% L21 Classics	Ila	6
20147026	CMA ROTARY FILE	P6 n20 6% L25 Classics	P6 n20 6% L25 Classics	Ila	6
20147027	CMA ROTARY FILE	P6 n20 6% L29 Classics	P6 n20 6% L29 Classics	Ila	6
20147031	CMA ROTARY FILE	P6 n30 6% L25 Classics	P6 n30 6% L25 Classics	Ila	6
20147036	CMA ROTARY FILE	P6 n40 7% L25 Classics	P6 n40 7% L25 Classics	Ila	6
20147040	CMA ROTARY FILE	P6 n17 2% L21 Classics	P6 n17 2% L21 Classics	Ila	6
20147041	CMA ROTARY FILE	P6 n17 2% L25 Classics	P6 n17 2% L25 Classics	Ila	6
20153001	2Shape	P6 2Shape TS1 n25 4% L21 Classics	P6 2Shape TS1 n25 4% L21 Classics	Ila	6
20153002	2Shape	P6 2Shape TS2 n25 6% L21 Classics	P6 2Shape TS2 n25 6% L21 Classics	Ila	6
20153003	2Shape	P6 2Shape F35 n35 6% L21 Classics	P6 2Shape F35 n35 6% L21 Classics	Ila	6
20153004	2Shape	P6 2Shape F40 n40 4% L21 Classics	P6 2Shape F40 n40 4% L21 Classics	Ila	6
20153011	2Shape	P6 2Shape TS1 n25 4% L25 Classics	P6 2Shape TS1 n25 4% L25 Classics	Ila	6
20153012	2Shape	P6 2Shape TS2 n25 6% L25 Classics	P6 2Shape TS2 n25 6% L25 Classics	Ila	6
20153013	2Shape	P6 2Shape F35 n35 6% L25 Classics	P6 2Shape F35 n35 6% L25 Classics	Ila	6
20153014	2Shape	P6 2Shape F40 n40 4% L25 Classics	P6 2Shape F40 n40 4% L25 Classics	Ila	6
20153021	2Shape	P6 2Shape TS1 n25 4% L31 Classics	P6 2Shape TS1 n25 4% L31 Classics	Ila	6
20153022	2Shape	P6 2Shape TS2 n25 6% L31 Classics	P6 2Shape TS2 n25 6% L31 Classics	Ila	6
20153023	2Shape	P6 2Shape F35 n35 6% L31 Classics	P6 2Shape F35 n35 6% L31 Classics	Ila	6
20153024	2Shape	P6 2Shape F40 n40 4% L31 Classics	P6 2Shape F40 n40 4% L31 Classics	Ila	6
20153031	2Shape	P4 2Shape 2xTS1+2xTS2 L21 Classics	P4 2Shape 2xTS1+2xTS2 L21 Classics	Ila	6
20153032	2Shape	P4 2Shape 2xTS1+2xTS2 L25 Classics	P4 2Shape 2xTS1+2xTS2 L25 Classics	Ila	6
20153033	2Shape	P4 2Shape 2xTS1+2xTS2 L31 Classics	P4 2Shape 2xTS1+2xTS2 L31 Classics	Ila	6
20953001	2Shape	B5 2Shape TS1 n25 4% L21 Classics sterile	B5 2Shape TS1 n25 4% L21 Classics sterile	Ila	6
20953002	2Shape	B5 2Shape TS2 n25 6% L21 Classics sterile	B5 2Shape TS2 n25 6% L21 Classics sterile	Ila	6
20953003	2Shape	B5 2Shape F35 n35 6% L21 Classics sterile	B5 2Shape F35 n35 6% L21 Classics sterile	Ila	6
20953004	2Shape	B5 2Shape F40 n40 4% L21 Classics sterile	B5 2Shape F40 n40 4% L21 Classics sterile	Ila	6
20953011	2Shape	B5 2Shape TS1 n25 4% L25 Classics sterile	B5 2Shape TS1 n25 4% L25 Classics sterile	Ila	6
20953012	2Shape	B5 2Shape TS2 n25 6% L25 Classics sterile	B5 2Shape TS2 n25 6% L25 Classics sterile	Ila	6
20953013	2Shape	B5 2Shape F35 n35 6% L25 Classics sterile	B5 2Shape F35 n35 6% L25 Classics sterile	Ila	6
20953014	2Shape	B5 2Shape F40 n40 4% L25 Classics sterile	B5 2Shape F40 n40 4% L25 Classics sterile	Ila	6

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA

Stéphane CLAUDE

Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

Micro-Mega SA
12 rue du Tunnel
25000 BESANCON
France

GMED (0459) reconnaît que son certificat CE est valide pour
les dispositifs médicaux décrits le 12 mai 2021

DocuSigned by:

GMED (0459) recognizes that its CE certificate is valid for the
medical devices listed on May 12, 2021



MicroMega

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

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20953021	2Shape	B5 2Shape TS1 n25 4% L31 Classics sterile	B5 2Shape TS1 n25 4% L31 Classics sterile	IIa	6
20953022	2Shape	B5 2Shape TS2 n25 6% L31 Classics sterile	B5 2Shape TS2 n25 6% L31 Classics sterile	IIa	6
20953023	2Shape	B5 2Shape F35 n35 6% L31 Classics sterile	B5 2Shape F35 n35 6% L31 Classics sterile	IIa	6
20953024	2Shape	B5 2Shape F40 n40 4% L31 Classics sterile	B5 2Shape F40 n40 4% L31 Classics sterile	IIa	6
20953031	2Shape	B4 2Shape 2xTS1+2xTS2 L21 Classics Sterile	B4 2Shape 2xTS1+2xTS2 L21 Classics Sterile	IIa	6
20953032	2Shape	B4 2Shape 2xTS1+2xTS2 L25 Classics Sterile	B4 2Shape 2xTS1+2xTS2 L25 Classics Sterile	IIa	6
20953033	2Shape	B4 2Shape 2xTS1+2xTS2 L31 Classics Sterile	B4 2Shape 2xTS1+2xTS2 L31 Classics Sterile	IIa	6
20953101	2Shape	B5 2Shape Procedure Pack L21 Classics sterile	B5 2Shape Procedure Pack L21 Classics sterile	IIa	6
20953102	2Shape	B5 2Shape Procedure Pack L25 Classics sterile	B5 2Shape Procedure Pack L25 Classics sterile	IIa	6
20953103	2Shape	B5 2Shape Procedure Pack L31 Classics sterile	B5 2Shape Procedure Pack L31 Classics sterile	IIa	6
20141001	ENDOFLARE	P4 ENDOFLARE n25 12% L15 Classics	P4 ENDOFLARE n25 12% L15 Classics	IIa	6
20941001	ENDOFLARE	B5 ENDOFLARE n25 12% L15 Classics sterile	B5 ENDOFLARE n25 12% L15 Classics sterile	IIa	6
20104001	ENGINE REAMERS	P6 Broches-Forets n006 L21 ISO M07	P6 Engine Reamers n006 L21 ISO M07	IIa	2
20104002	ENGINE REAMERS	P6 Broches-Forets n006 L25 ISO M07	P6 Engine Reamers n006 L25 ISO M07	IIa	2
20104003	ENGINE REAMERS	P6 Broches-Forets n006 L29 ISO M07	P6 Engine Reamers n006 L29 ISO M07	IIa	2
20104004	ENGINE REAMERS	P6 Broches-Forets n008 L21 ISO M07	P6 Engine Reamers n008 L21 ISO M07	IIa	2
20104005	ENGINE REAMERS	P6 Broches-Forets n008 L25 ISO M07	P6 Engine Reamers n008 L25 ISO M07	IIa	2
20104006	ENGINE REAMERS	P6 Broches-Forets n008 L29 ISO M07	P6 Engine Reamers n008 L29 ISO M07	IIa	2
20104007	ENGINE REAMERS	P6 Broches-Forets n010 L21 ISO M07	P6 Engine Reamers n010 L21 ISO M07	IIa	2
20104008	ENGINE REAMERS	P6 Broches-Forets n010 L25 ISO M07	P6 Engine Reamers n010 L25 ISO M07	IIa	2
20104009	ENGINE REAMERS	P6 Broches-Forets n010 L29 ISO M07	P6 Engine Reamers n010 L29 ISO M07	IIa	2
20104010	ENGINE REAMERS	P6 Broches-Forets n015 L21 ISO M07	P6 Engine Reamers n015 L21 ISO M07	IIa	2
20104011	ENGINE REAMERS	P6 Broches-Forets n015 L25 ISO M07	P6 Engine Reamers n015 L25 ISO M07	IIa	2
20104012	ENGINE REAMERS	P6 Broches-Forets n015 L29 ISO M07	P6 Engine Reamers n015 L29 ISO M07	IIa	2
20104013	ENGINE REAMERS	P6 Broches-Forets n020 L21 ISO M07	P6 Engine Reamers n020 L21 ISO M07	IIa	2
20104014	ENGINE REAMERS	P6 Broches-Forets n020 L25 ISO M07	P6 Engine Reamers n020 L25 ISO M07	IIa	2
20104015	ENGINE REAMERS	P6 Broches-Forets n020 L29 ISO M07	P6 Engine Reamers n020 L29 ISO M07	IIa	2
20104016	ENGINE REAMERS	P6 Broches-Forets n025 L21 ISO M07	P6 Engine Reamers n025 L21 ISO M07	IIa	2
20104017	ENGINE REAMERS	P6 Broches-Forets n025 L25 ISO M07	P6 Engine Reamers n025 L25 ISO M07	IIa	2
20104018	ENGINE REAMERS	P6 Broches-Forets n025 L29 ISO M07	P6 Engine Reamers n025 L29 ISO M07	IIa	2
20104019	ENGINE REAMERS	P6 Broches-Forets n030 L21 ISO M07	P6 Engine Reamers n030 L21 ISO M07	IIa	2
20104020	ENGINE REAMERS	P6 Broches-Forets n030 L25 ISO M07	P6 Engine Reamers n030 L25 ISO M07	IIa	2
20104021	ENGINE REAMERS	P6 Broches-Forets n030 L29 ISO M07	P6 Engine Reamers n030 L29 ISO M07	IIa	2
20104022	ENGINE REAMERS	P6 Broches-Forets n035 L21 ISO M07	P6 Engine Reamers n035 L21 ISO M07	IIa	2
20104023	ENGINE REAMERS	P6 Broches-Forets n035 L25 ISO M07	P6 Engine Reamers n035 L25 ISO M07	IIa	2
20104024	ENGINE REAMERS	P6 Broches-Forets n035 L29 ISO M07	P6 Engine Reamers n035 L29 ISO M07	IIa	2
20104025	ENGINE REAMERS	P6 Broches-Forets n040 L21 ISO M07	P6 Engine Reamers n040 L21 ISO M07	IIa	2
20104026	ENGINE REAMERS	P6 Broches-Forets n040 L25 ISO M07	P6 Engine Reamers n040 L25 ISO M07	IIa	2
20104027	ENGINE REAMERS	P6 Broches-Forets n040 L29 ISO M07	P6 Engine Reamers n040 L29 ISO M07	IIa	2
20104028	ENGINE REAMERS	P6 Broches-Forets n045 L21 ISO M07	P6 Engine Reamers n045 L21 ISO M07	IIa	2
20104029	ENGINE REAMERS	P6 Broches-Forets n045 L25 ISO M07	P6 Engine Reamers n045 L25 ISO M07	IIa	2
20104030	ENGINE REAMERS	P6 Broches-Forets n045 L29 ISO M07	P6 Engine Reamers n045 L29 ISO M07	IIa	2
20104031	ENGINE REAMERS	P6 Broches-Forets n050 L21 ISO M07	P6 Engine Reamers n050 L21 ISO M07	IIa	2
20104032	ENGINE REAMERS	P6 Broches-Forets n050 L25 ISO M07	P6 Engine Reamers n050 L25 ISO M07	IIa	2
20104033	ENGINE REAMERS	P6 Broches-Forets n050 L29 ISO M07	P6 Engine Reamers n050 L29 ISO M07	IIa	2
20104034	ENGINE REAMERS	P6 Broches-Forets n055 L21 ISO M07	P6 Engine Reamers n055 L21 ISO M07	IIa	2
20104035	ENGINE REAMERS	P6 Broches-Forets n055 L25 ISO M07	P6 Engine Reamers n055 L25 ISO M07	IIa	2
20104036	ENGINE REAMERS	P6 Broches-Forets n055 L29 ISO M07	P6 Engine Reamers n055 L29 ISO M07	IIa	2
20104037	ENGINE REAMERS	P6 Broches-Forets n060 L21 ISO M07	P6 Engine Reamers n060 L21 ISO M07	IIa	2
20104038	ENGINE REAMERS	P6 Broches-Forets n060 L25 ISO M07	P6 Engine Reamers n060 L25 ISO M07	IIa	2
20104039	ENGINE REAMERS	P6 Broches-Forets n060 L29 ISO M07	P6 Engine Reamers n060 L29 ISO M07	IIa	2
20104040	ENGINE REAMERS	P6 Broches-Forets n070 L21 ISO M07	P6 Engine Reamers n070 L21 ISO M07	IIa	2
20104041	ENGINE REAMERS	P6 Broches-Forets n070 L25 ISO M07	P6 Engine Reamers n070 L25 ISO M07	IIa	2
20104042	ENGINE REAMERS	P6 Broches-Forets n070 L29 ISO M07	P6 Engine Reamers n070 L29 ISO M07	IIa	2
20104043	ENGINE REAMERS	P6 Broches-Forets n080 L21 ISO M07	P6 Engine Reamers n080 L21 ISO M07	IIa	2
20104044	ENGINE REAMERS	P6 Broches-Forets n080 L25 ISO M07	P6 Engine Reamers n080 L25 ISO M07	IIa	2
20104045	ENGINE REAMERS	P6 Broches-Forets n080 L29 ISO M07	P6 Engine Reamers n080 L29 ISO M07	IIa	2

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA

Stéphane CLAUDE

Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

Micro-Mega SA certifie que les produits suivants sont conformes à l'annexe I et VII de la directive 93/42 CEE relative aux dispositifs médicaux, en tenant compte de toutes les normes harmonisées européennes applicables et aux transpositions en droit national de chaque état et que son système d'assurance qualité, selon l'annexe II excluant le point 4 de la directive 93/42 CEE, est approuvé (Attestation CE n°8881 délivrée par l'organisme notifié GMED).

Micro-Mega SA certifies that the products listed below conform to annex I and VII of the Directive 93/42/EEC for medical devices, taking into account all applicable European harmonised standards and national laws for each state and that its full quality assurance system, according annex II excluding point 4 of the Directive 93/42/EEC, is approved (CE certificate n°8881 delivered by notified body GMED).

20104046	ENGINE REAMERS	P6 Broches-Forets n090 L21 ISO M07	P6 Engine Reamers n090 L21 ISO M07	Ila	2
20104047	ENGINE REAMERS	P6 Broches-Forets n090 L25 ISO M07	P6 Engine Reamers n090 L25 ISO M07	Ila	2
20104048	ENGINE REAMERS	P6 Broches-Forets n090 L29 ISO M07	P6 Engine Reamers n090 L29 ISO M07	Ila	2
20104049	ENGINE REAMERS	P6 Broches-Forets n100 L21 ISO M07	P6 Engine Reamers n100 L21 ISO M07	Ila	2
20104050	ENGINE REAMERS	P6 Broches-Forets n100 L25 ISO M07	P6 Engine Reamers n100 L25 ISO M07	Ila	2
20104051	ENGINE REAMERS	P6 Broches-Forets n100 L29 ISO M07	P6 Engine Reamers n100 L29 ISO M07	Ila	2
20104052	ENGINE REAMERS	P6 Broches-Forets n110 L21 ISO M07	P6 Engine Reamers n110 L21 ISO M07	Ila	2
20104053	ENGINE REAMERS	P6 Broches-Forets n110 L25 ISO M07	P6 Engine Reamers n110 L25 ISO M07	Ila	2
20104054	ENGINE REAMERS	P6 Broches-Forets n110 L29 ISO M07	P6 Engine Reamers n110 L29 ISO M07	Ila	2
20104055	ENGINE REAMERS	P6 Broches-Forets n120 L21 ISO M07	P6 Engine Reamers n120 L21 ISO M07	Ila	2
20104056	ENGINE REAMERS	P6 Broches-Forets n120 L25 ISO M07	P6 Engine Reamers n120 L25 ISO M07	Ila	2
20104057	ENGINE REAMERS	P6 Broches-Forets n120 L29 ISO M07	P6 Engine Reamers n120 L29 ISO M07	Ila	2
20104058	ENGINE REAMERS	P6 Broches-Forets n130 L21 ISO M07	P6 Engine Reamers n130 L21 ISO M07	Ila	2
20104059	ENGINE REAMERS	P6 Broches-Forets n130 L25 ISO M07	P6 Engine Reamers n130 L25 ISO M07	Ila	2
20104060	ENGINE REAMERS	P6 Broches-Forets n130 L29 ISO M07	P6 Engine Reamers n130 L29 ISO M07	Ila	2
20104061	ENGINE REAMERS	P6 Broches-Forets n140 L21 ISO M07	P6 Engine Reamers n140 L21 ISO M07	Ila	2
20104062	ENGINE REAMERS	P6 Broches-Forets n140 L25 ISO M07	P6 Engine Reamers n140 L25 ISO M07	Ila	2
20104063	ENGINE REAMERS	P6 Broches-Forets n140 L29 ISO M07	P6 Engine Reamers n140 L29 ISO M07	Ila	2
20104064	ENGINE REAMERS	P6 Broches-Forets n015/040 L21 ISO M07	P6 Engine Reamers n015/040 L21 ISO M07	Ila	2
20104065	ENGINE REAMERS	P6 Broches-Forets n015/040 L25 ISO M07	P6 Engine Reamers n015/040 L25 ISO M07	Ila	2
20104066	ENGINE REAMERS	P6 Broches-Forets n015/040 L29 ISO M07	P6 Engine Reamers n015/040 L29 ISO M07	Ila	2
20104067	ENGINE REAMERS	P6 Broches-Forets n045/080 L21 ISO M07	P6 Engine Reamers n045/080 L21 ISO M07	Ila	2
20104068	ENGINE REAMERS	P6 Broches-Forets n045/080 L25 ISO M07	P6 Engine Reamers n045/080 L25 ISO M07	Ila	2
20155002	GENGIRO	P6 GenGIRO G25 L21 Classics GenENDO	P6 GenGIRO G25 L21 Classics GenENDO	Ila	2
20155005	GENGIRO	P6 GenGIRO G40 L21 Classics GenENDO	P6 GenGIRO G40 L21 Classics GenENDO	Ila	2
20155007	GENGIRO	P6 GenGIRO G50 L21 Classics GenENDO	P6 GenGIRO G50 L21 Classics GenENDO	Ila	2
20155008	GENGIRO	P6 GenGIRO Asst L21 G25-G40-G50 GenENDO	P6 GenGIRO Asst L21 G25-G40-G50 GenENDO	Ila	2
20155012	GENGIRO	P6 GenGIRO G25 L25 Classics GenENDO	P6 GenGIRO G25 L25 Classics GenENDO	Ila	2
20155015	GENGIRO	P6 GenGIRO G40 L25 Classics GenENDO	P6 GenGIRO G40 L25 Classics GenENDO	Ila	2
20155017	GENGIRO	P6 GenGIRO G50 L25 Classics GenENDO	P6 GenGIRO G50 L25 Classics GenENDO	Ila	2
20155018	GENGIRO	P6 GenGIRO Asst L25 G25-G40-G50 GenENDO	P6 GenGIRO Asst L25 G25-G40-G50 GenENDO	Ila	2
20155022	GENGIRO	P6 GenGIRO G25 L31 Classics GenENDO	P6 GenGIRO G25 L31 Classics GenENDO	Ila	2
20155025	GENGIRO	P6 GenGIRO G40 L31 Classics GenENDO	P6 GenGIRO G40 L31 Classics GenENDO	Ila	2
20155027	GENGIRO	P6 GenGIRO G50 L31 Classics GenENDO	P6 GenGIRO G50 L31 Classics GenENDO	Ila	2
20155028	GENGIRO	P6 GenGIRO Asst L31 G25-G40-G50 GenENDO	P6 GenGIRO Asst L31 G25-G40-G50 GenENDO	Ila	2
20955002	GENGIRO	B5 GenGIRO G25 L21 Classics GenENDO sterile	B5 GenGIRO G25 L21 Classics GenENDO sterile	Ila	2
20955005	GENGIRO	B5 GenGIRO G40 L21 Classics GenENDO sterile	B5 GenGIRO G40 L21 Classics GenENDO sterile	Ila	2
20955007	GENGIRO	B5 GenGIRO G50 L21 Classics GenENDO sterile	B5 GenGIRO G50 L21 Classics GenENDO sterile	Ila	2
20955008	GENGIRO	B5 GenGIRO Asst L21 G25-G40-G50 GenENDO sterile	B5 GenGIRO Asst L21 G25-G40-G50 GenENDO sterile	Ila	2
20955012	GENGIRO	B5 GenGIRO G25 L25 Classics GenENDO sterile	B5 GenGIRO G25 L25 Classics GenENDO sterile	Ila	2
20955015	GENGIRO	B5 GenGIRO G40 L25 Classics GenENDO sterile	B5 GenGIRO G40 L25 Classics GenENDO sterile	Ila	2
20955017	GENGIRO	B5 GenGIRO G50 L25 Classics GenENDO sterile	B5 GenGIRO G50 L25 Classics GenENDO sterile	Ila	2
20955018	GENGIRO	B5 GenGIRO Asst L25 G25-G40-G50 GenENDO sterile	B5 GenGIRO Asst L25 G25-G40-G50 GenENDO sterile	Ila	2
20955022	GENGIRO	B5 GenGIRO G25 L31 Classics GenENDO sterile	B5 GenGIRO G25 L31 Classics GenENDO sterile	Ila	2
20955025	GENGIRO	B5 GenGIRO G40 L31 Classics GenENDO sterile	B5 GenGIRO G40 L31 Classics GenENDO sterile	Ila	2
20955027	GENGIRO	B5 GenGIRO G50 L31 Classics GenENDO sterile	B5 GenGIRO G50 L31 Classics GenENDO sterile	Ila	2
20955028	GENGIRO	B5 GenGIRO Asst L31 G25-G40-G50 GenENDO sterile	B5 GenGIRO Asst L31 G25-G40-G50 GenENDO sterile	Ila	2
20154001	GENTAPER	P6 GenTAPER SX n19 L19 GenENDO	P6 GenTAPER SX n19 L19 GenENDO	Ila	6
20154002	GENTAPER	P6 GenTAPER S1 n17 L21 GenENDO	P6 GenTAPER S1 n17 L21 GenENDO	Ila	6
20154003	GENTAPER	P6 GenTAPER S2 n20 L21 GenENDO	P6 GenTAPER S2 n20 L21 GenENDO	Ila	6
20154004	GENTAPER	P6 GenTAPER F1 n20 L21 GenENDO	P6 GenTAPER F1 n20 L21 GenENDO	Ila	6
20154005	GENTAPER	P6 GenTAPER F2 n25 L21 GenENDO	P6 GenTAPER F2 n25 L21 GenENDO	Ila	6
20154006	GENTAPER	P6 GenTAPER F3 n30 L21 GenENDO	P6 GenTAPER F3 n30 L21 GenENDO	Ila	6
20154012	GENTAPER	P6 GenTAPER S1 n17 L25 GenENDO	P6 GenTAPER S1 n17 L25 GenENDO	Ila	6
20154013	GENTAPER	P6 GenTAPER S2 n20 L25 GenENDO	P6 GenTAPER S2 n20 L25 GenENDO	Ila	6
20154014	GENTAPER	P6 GenTAPER F1 n20 L25 GenENDO	P6 GenTAPER F1 n20 L25 GenENDO	Ila	6
20154015	GENTAPER	P6 GenTAPER F2 n25 L25 GenENDO	P6 GenTAPER F2 n25 L25 GenENDO	Ila	6

Micro-Mega SA
12 rue du Tunnel
25000 BESANCON
France

GMED (0459) reconnaît que son certificat CE est valide pour
les dispositifs médicaux décrits le 12 mai 2021

GMED (0459) recognizes that its EC certificate is valid for the
medical devices listed on May 12, 2021

 **COLTENE**
MicroMega

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

Micro-Mega SA certifie que les produits suivants sont conformes à l'annexe I et VII de la directive 93/42 CEE relative aux dispositifs médicaux, en tenant compte de toutes les normes harmonisées européennes applicables et aux transpositions en droit national de chaque état et que son système d'assurance qualité, selon l'annexe II excluant le point 4 de la directive 93/42 CEE, est approuvé (Attestation CE n°8881 délivrée par l'organisme notifié GMED).

Micro-Mega SA certifies that the products listed below conform to annex I and VII of the Directive 93/42/EEC for medical devices, taking into account all applicable European harmonised standards and national laws for each state and that its full quality assurance system, according annex II excluding point 4 of the Directive 93/42/EEC, is approved (CE certificate n°8881 delivered by notified body GMED).

20154016	GENTAPER	P6 GenTAPER F3 n30 L25 GenENDO	P6 GenTAPER F3 n30 L25 GenENDO	Ila	6
20154022	GENTAPER	P6 GenTAPER S1 n17 L31 GenENDO	P6 GenTAPER S1 n17 L31 GenENDO	Ila	6
20154023	GENTAPER	P6 GenTAPER S2 n20 L31 GenENDO	P6 GenTAPER S2 n20 L31 GenENDO	Ila	6
20154024	GENTAPER	P6 GenTAPER F1 n20 L31 GenENDO	P6 GenTAPER F1 n20 L31 GenENDO	Ila	6
20154025	GENTAPER	P6 GenTAPER F2 n25 L31 GenENDO	P6 GenTAPER F2 n25 L31 GenENDO	Ila	6
20154026	GENTAPER	P6 GenTAPER F3 n30 L31 GenENDO	P6 GenTAPER F3 n30 L31 GenENDO	Ila	6
20154030	GENTAPER	P6 GenTAPER L21 Sequence GenENDO	P6 GenTAPER L21 Sequence GenENDO	Ila	6
20154031	GENTAPER	P6 GenTAPER L25 Sequence GenENDO	P6 GenTAPER L25 Sequence GenENDO	Ila	6
20154032	GENTAPER	P6 GenTAPER L31 Sequence GenENDO	P6 GenTAPER L31 Sequence GenENDO	Ila	6
20954001	GENTAPER	B5 GenTAPER SX n19 L19 GenENDO sterile	B5 GenTAPER SX n19 L19 GenENDO sterile	Ila	6
20954002	GENTAPER	B5 GenTAPER S1 n17 L21 GenENDO sterile	B5 GenTAPER S1 n17 L21 GenENDO sterile	Ila	6
20954003	GENTAPER	B5 GenTAPER S2 n20 L21 GenENDO sterile	B5 GenTAPER S2 n20 L21 GenENDO sterile	Ila	6
20954004	GENTAPER	B5 GenTAPER F1 n20 L21 GenENDO sterile	B5 GenTAPER F1 n20 L21 GenENDO sterile	Ila	6
20954005	GENTAPER	B5 GenTAPER F2 n25 L21 GenENDO sterile	B5 GenTAPER F2 n25 L21 GenENDO sterile	Ila	6
20954006	GENTAPER	B5 GenTAPER F3 n30 L21 GenENDO sterile	B5 GenTAPER F3 n30 L21 GenENDO sterile	Ila	6
20954012	GENTAPER	B5 GenTAPER S1 n17 L25 GenENDO sterile	B5 GenTAPER S1 n17 L25 GenENDO sterile	Ila	6
20954013	GENTAPER	B5 GenTAPER S2 n20 L25 GenENDO sterile	B5 GenTAPER S2 n20 L25 GenENDO sterile	Ila	6
20954014	GENTAPER	B5 GenTAPER F1 n20 L25 GenENDO sterile	B5 GenTAPER F1 n20 L25 GenENDO sterile	Ila	6
20954015	GENTAPER	B5 GenTAPER F2 n25 L25 GenENDO sterile	B5 GenTAPER F2 n25 L25 GenENDO sterile	Ila	6
20954016	GENTAPER	B5 GenTAPER F3 n30 L25 GenENDO sterile	B5 GenTAPER F3 n30 L25 GenENDO sterile	Ila	6
20954022	GENTAPER	B5 GenTAPER S1 n17 L31 GenENDO sterile	B5 GenTAPER S1 n17 L31 GenENDO sterile	Ila	6
20954023	GENTAPER	B5 GenTAPER S2 n20 L31 GenENDO sterile	B5 GenTAPER S2 n20 L31 GenENDO sterile	Ila	6
20954024	GENTAPER	B5 GenTAPER F1 n20 L31 GenENDO sterile	B5 GenTAPER F1 n20 L31 GenENDO sterile	Ila	6
20954025	GENTAPER	B5 GenTAPER F2 n25 L31 GenENDO sterile	B5 GenTAPER F2 n25 L31 GenENDO sterile	Ila	6
20954026	GENTAPER	B5 GenTAPER F3 n30 L31 GenENDO sterile	B5 GenTAPER F3 n30 L31 GenENDO sterile	Ila	6
20954030	GENTAPER	B5 GenTAPER L21 Sequence GenENDO sterile	B5 GenTAPER L21 Sequence GenENDO sterile	Ila	6
20954031	GENTAPER	B5 GenTAPER L25 Sequence GenENDO sterile	B5 GenTAPER L25 Sequence GenENDO sterile	Ila	6
20954032	GENTAPER	B5 GenTAPER L31 Sequence GenENDO sterile	B5 GenTAPER L31 Sequence GenENDO sterile	Ila	6
20148001	G-FILES	P4 G-Files Asst L21 2xG1 2xG2 Classics	P4 G-Files Asst L21 2xG1 2xG2 Classics	Ila	6
20148002	G-FILES	P4 G-Files Asst L25 2xG1 2xG2 Classics	P4 G-Files Asst L25 2xG1 2xG2 Classics	Ila	6
20148003	G-FILES	P4 G-Files Asst L29 2xG1 2xG2 Classics	P4 G-Files Asst L29 2xG1 2xG2 Classics	Ila	6
20148011	G-FILES	P4 G-Files G1 n12 L21 3% Classics	P4 G-Files G1 n12 L21 3% Classics	Ila	6
20148012	G-FILES	P4 G-Files G1 n12 L25 3% Classics	P4 G-Files G1 n12 L25 3% Classics	Ila	6
20148013	G-FILES	P4 G-Files G1 n12 L29 3% Classics	P4 G-Files G1 n12 L29 3% Classics	Ila	6
20148021	G-FILES	P4 G-Files G2 n17 L21 3% Classics	P4 G-Files G2 n17 L21 3% Classics	Ila	6
20148022	G-FILES	P4 G-Files G2 n17 L25 3% Classics	P4 G-Files G2 n17 L25 3% Classics	Ila	6
20148023	G-FILES	P4 G-Files G2 n17 L29 3% Classics	P4 G-Files G2 n17 L29 3% Classics	Ila	6
20948011	G-FILES	B5 G-Files G1 n012 3% L21 Classics sterile	B5 G-Files G1 n012 3% L21 Classics sterile	Ila	6
20948012	G-FILES	B5 G-Files G1 n012 3% L25 Classics sterile	B5 G-Files G1 n012 3% L25 Classics sterile	Ila	6
20948013	G-FILES	B5 G-Files G1 n012 3% L29 Classics sterile	B5 G-Files G1 n012 3% L29 Classics sterile	Ila	6
20948021	G-FILES	B5 G-Files G2 n017 3% L21 Classics sterile	B5 G-Files G2 n017 3% L21 Classics sterile	Ila	6
20948022	G-FILES	B5 G-Files G2 n017 3% L25 Classics sterile	B5 G-Files G2 n017 3% L25 Classics sterile	Ila	6
20948023	G-FILES	B5 G-Files G2 n017 3% L29 Classics sterile	B5 G-Files G2 n017 3% L29 Classics sterile	Ila	6
20105001	GIRO-FILES	P6 Giro-files n008 L21 ISO M07	P6 Giro-files n008 L21 ISO M07	Ila	2
20105002	GIRO-FILES	P6 Giro-files n008 L25 ISO M07	P6 Giro-files n008 L25 ISO M07	Ila	2
20105003	GIRO-FILES	P6 Giro-files n008 L29 ISO M07	P6 Giro-files n008 L29 ISO M07	Ila	2
20105004	GIRO-FILES	P6 Giro-files n010 L21 ISO M07	P6 Giro-files n010 L21 ISO M07	Ila	2
20105005	GIRO-FILES	P6 Giro-files n010 L25 ISO M07	P6 Giro-files n010 L25 ISO M07	Ila	2
20105006	GIRO-FILES	P6 Giro-files n010 L29 ISO M07	P6 Giro-files n010 L29 ISO M07	Ila	2
20105007	GIRO-FILES	P6 Giro-files n015 L21 ISO M07	P6 Giro-files n015 L21 ISO M07	Ila	2
20105008	GIRO-FILES	P6 Giro-files n015 L25 ISO M07	P6 Giro-files n015 L25 ISO M07	Ila	2
20105009	GIRO-FILES	P6 Giro-files n015 L29 ISO M07	P6 Giro-files n015 L29 ISO M07	Ila	2
20105010	GIRO-FILES	P6 Giro-files n020 L21 ISO M07	P6 Giro-files n020 L21 ISO M07	Ila	2
20105011	GIRO-FILES	P6 Giro-files n020 L25 ISO M07	P6 Giro-files n020 L25 ISO M07	Ila	2
20105012	GIRO-FILES	P6 Giro-files n020 L29 ISO M07	P6 Giro-files n020 L29 ISO M07	Ila	2
20105013	GIRO-FILES	P6 Giro-files n025 L21 ISO M07	P6 Giro-files n025 L21 ISO M07	Ila	2
20105014	GIRO-FILES	P6 Giro-files n025 L25 ISO M07	P6 Giro-files n025 L25 ISO M07	Ila	2

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA
Stéphane CLAUDE
Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

Micro-Mega SA
12 rue du Tunnel
25000 BESANCON
France

GMED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits le 12 mai 2021

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed on May 12, 2021

COLTENE
MicroMega

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

Micro-Mega SA certifie que les produits suivants sont conformes à l'annexe I et VII de la directive 93/42 CEE relative aux dispositifs médicaux, en tenant compte de toutes les normes harmonisées européennes applicables et aux transpositions en droit national de chaque état et que son système d'assurance qualité, selon l'annexe II excluant le point 4 de la directive 93/42 CEE, est approuvé (Attestation CE n°8881 délivrée par l'organisme notifié GMED).

Micro-Mega SA certifies that the products listed below conform to annex I and VII of the Directive 93/42/EEC for medical devices, taking into account all applicable European harmonised standards and national laws for each state and that its full quality assurance system, according annex II excluding point 4 of the Directive 93/42/EEC, is approved (CE certificate n°8881 delivered by notified body GMED).

20105015	GIRO-FILES	P6 Giro-files n025 L29 ISO M07	P6 Giro-files n025 L29 ISO M07	Ila	2
20105016	GIRO-FILES	P6 Giro-files n030 L21 ISO M07	P6 Giro-files n030 L21 ISO M07	Ila	2
20105017	GIRO-FILES	P6 Giro-files n030 L25 ISO M07	P6 Giro-files n030 L25 ISO M07	Ila	2
20105018	GIRO-FILES	P6 Giro-files n030 L29 ISO M07	P6 Giro-files n030 L29 ISO M07	Ila	2
20105019	GIRO-FILES	P6 Giro-files n035 L21 ISO M07	P6 Giro-files n035 L21 ISO M07	Ila	2
20105020	GIRO-FILES	P6 Giro-files n035 L25 ISO M07	P6 Giro-files n035 L25 ISO M07	Ila	2
20105021	GIRO-FILES	P6 Giro-files n035 L29 ISO M07	P6 Giro-files n035 L29 ISO M07	Ila	2
20105022	GIRO-FILES	P6 Giro-files n040 L21 ISO M07	P6 Giro-files n040 L21 ISO M07	Ila	2
20105023	GIRO-FILES	P6 Giro-files n040 L25 ISO M07	P6 Giro-files n040 L25 ISO M07	Ila	2
20105024	GIRO-FILES	P6 Giro-files n040 L29 ISO M07	P6 Giro-files n040 L29 ISO M07	Ila	2
20105025	GIRO-FILES	P6 Giro-files n045 L21 ISO M07	P6 Giro-files n045 L21 ISO M07	Ila	2
20105026	GIRO-FILES	P6 Giro-files n045 L25 ISO M07	P6 Giro-files n045 L25 ISO M07	Ila	2
20105027	GIRO-FILES	P6 Giro-files n045 L29 ISO M07	P6 Giro-files n045 L29 ISO M07	Ila	2
20105028	GIRO-FILES	P6 Giro-files n050 L21 ISO M07	P6 Giro-files n050 L21 ISO M07	Ila	2
20105029	GIRO-FILES	P6 Giro-files n050 L25 ISO M07	P6 Giro-files n050 L25 ISO M07	Ila	2
20105030	GIRO-FILES	P6 Giro-files n050 L29 ISO M07	P6 Giro-files n050 L29 ISO M07	Ila	2
20105031	GIRO-FILES	P6 Giro-files n055 L21 ISO M07	P6 Giro-files n055 L21 ISO M07	Ila	2
20105032	GIRO-FILES	P6 Giro-files n055 L25 ISO M07	P6 Giro-files n055 L25 ISO M07	Ila	2
20105033	GIRO-FILES	P6 Giro-files n055 L29 ISO M07	P6 Giro-files n055 L29 ISO M07	Ila	2
20105034	GIRO-FILES	P6 Giro-files n060 L21 ISO M07	P6 Giro-files n060 L21 ISO M07	Ila	2
20105035	GIRO-FILES	P6 Giro-files n060 L25 ISO M07	P6 Giro-files n060 L25 ISO M07	Ila	2
20105036	GIRO-FILES	P6 Giro-files n060 L29 ISO M07	P6 Giro-files n060 L29 ISO M07	Ila	2
20105037	GIRO-FILES	P6 Giro-files n070 L21 ISO M07	P6 Giro-files n070 L21 ISO M07	Ila	2
20105038	GIRO-FILES	P6 Giro-files n070 L25 ISO M07	P6 Giro-files n070 L25 ISO M07	Ila	2
20105039	GIRO-FILES	P6 Giro-files n070 L29 ISO M07	P6 Giro-files n070 L29 ISO M07	Ila	2
20105040	GIRO-FILES	P6 Giro-files n080 L21 ISO M07	P6 Giro-files n080 L21 ISO M07	Ila	2
20105041	GIRO-FILES	P6 Giro-files n080 L25 ISO M07	P6 Giro-files n080 L25 ISO M07	Ila	2
20105042	GIRO-FILES	P6 Giro-files n080 L29 ISO M07	P6 Giro-files n080 L29 ISO M07	Ila	2
20105043	GIRO-FILES	P6 Giro-files n090 L21 ISO M07	P6 Giro-files n090 L21 ISO M07	Ila	2
20105044	GIRO-FILES	P6 Giro-files n090 L25 ISO M07	P6 Giro-files n090 L25 ISO M07	Ila	2
20105045	GIRO-FILES	P6 Giro-files n090 L29 ISO M07	P6 Giro-files n090 L29 ISO M07	Ila	2
20105061	GIRO-FILES	P6 Giro-files 015/040 L21 ISO M07	P6 Giro-files 015/040 L21 ISO M07	Ila	2
20105062	GIRO-FILES	P6 Giro-files 015/040 L25 ISO M07	P6 Giro-files 015/040 L25 ISO M07	Ila	2
20105063	GIRO-FILES	P6 Giro-files 015/040 L29 ISO M07	P6 Giro-files 015/040 L29 ISO M07	Ila	2
20105064	GIRO-FILES	P6 Giro-files 045/080 L21 ISO M07	P6 Giro-files 045/080 L21 ISO M07	Ila	2
20105065	GIRO-FILES	P6 Giro-files 045/080 L25 ISO M07	P6 Giro-files 045/080 L25 ISO M07	Ila	2
20105066	GIRO-FILES	P6 Giro-files 045/080 L29 ISO M07	P6 Giro-files 045/080 L29 ISO M07	Ila	2
20113001	GIROMATIC CLEANSERS	P12 Alesoirs Giro n015 L21 ISO M07	P12 Giromatic Cleansers n015 L21 ISO M07	Ila	2
20113002	GIROMATIC CLEANSERS	P12 Alesoirs Giro n015 L25 ISO M07	P12 Giromatic Cleansers n015 L25 ISO M07	Ila	2
20113004	GIROMATIC CLEANSERS	P12 Alesoirs Giro n020 L21 ISO M07	P12 Giromatic Cleansers n020 L21 ISO M07	Ila	2
20113005	GIROMATIC CLEANSERS	P12 Alesoirs Giro n020 L25 ISO M07	P12 Giromatic Cleansers n020 L25 ISO M07	Ila	2
20113007	GIROMATIC CLEANSERS	P12 Alesoirs Giro n025 L21 ISO M07	P12 Giromatic Cleansers n025 L21 ISO M07	Ila	2
20113008	GIROMATIC CLEANSERS	P12 Alesoirs Giro n025 L25 ISO M07	P12 Giromatic Cleansers n025 L25 ISO M07	Ila	2
20113010	GIROMATIC CLEANSERS	P12 Alesoirs Giro n030 L21 ISO M07	P12 Giromatic Cleansers n030 L21 ISO M07	Ila	2
20113011	GIROMATIC CLEANSERS	P12 Alesoirs Giro n030 L25 ISO M07	P12 Giromatic Cleansers n030 L25 ISO M07	Ila	2
20113013	GIROMATIC CLEANSERS	P12 Alesoirs Giro n035 L21 ISO M07	P12 Giromatic Cleansers n035 L21 ISO M07	Ila	2
20113014	GIROMATIC CLEANSERS	P12 Alesoirs Giro n035 L25 ISO M07	P12 Giromatic Cleansers n035 L25 ISO M07	Ila	2
20113016	GIROMATIC CLEANSERS	P12 Alesoirs Giro n040 L21 ISO M07	P12 Giromatic Cleansers n040 L21 ISO M07	Ila	2
20113017	GIROMATIC CLEANSERS	P12 Alesoirs Giro n040 L25 ISO M07	P12 Giromatic Cleansers n040 L25 ISO M07	Ila	2
20113019	GIROMATIC CLEANSERS	P12 Alesoirs Giro n045 L21 ISO M07	P12 Giromatic Cleansers n045 L21 ISO M07	Ila	2
20113020	GIROMATIC CLEANSERS	P12 Alesoirs Giro n045 L25 ISO M07	P12 Giromatic Cleansers n045 L25 ISO M07	Ila	2
20113022	GIROMATIC CLEANSERS	P12 Alesoirs Giro n050 L21 ISO M07	P12 Giromatic Cleansers n050 L21 ISO M07	Ila	2
20113023	GIROMATIC CLEANSERS	P12 Alesoirs Giro n050 L25 ISO M07	P12 Giromatic Cleansers n050 L25 ISO M07	Ila	2
20109001	HELI-GIRO-FILES	P6 Heli-Giro-Files n015 L21 M07 ISO	P6 Heli-Giro-Files n015 L21 M07 ISO	Ila	2
20109002	HELI-GIRO-FILES	P6 Heli-Giro-Files n015 L25 M07 ISO	P6 Heli-Giro-Files n015 L25 M07 ISO	Ila	2
20109004	HELI-GIRO-FILES	P6 Heli-Giro-Files n020 L21 M07 ISO	P6 Heli-Giro-Files n020 L21 M07 ISO	Ila	2
20109005	HELI-GIRO-FILES	P6 Heli-Giro-Files n020 L25 M07 ISO	P6 Heli-Giro-Files n020 L25 M07 ISO	Ila	2

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA

Stéphane CLAUDE

Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

Micro-Mega SA
12 rue du Tunnel
25000 BESANCON
France

GMED (0459) reconnaît que son certificat CE est valide pour
les dispositifs médicaux décrits le 12 mai 2021

GMED (0459) recognizes that its EC certificate is valid for the
medical devices listed on May 12, 2021

 **COLTENE**
MicroMega

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

Micro-Mega SA certifie que les produits suivants sont conformes à l'annexe I et VII de la directive 93/42 CEE relative aux dispositifs médicaux, en tenant compte de toutes les normes harmonisées européennes applicables et aux transpositions en droit national de chaque état et que son système d'assurance qualité, selon l'annexe II excluant le point 4 de la directive 93/42 CEE, est approuvé (Attestation CE n°8881 délivrée par l'organisme notifié GMED).

Micro-Mega SA certifies that the products listed below conform to annex I and VII of the Directive 93/42/EEC for medical devices, taking into account all applicable European harmonised standards and national laws for each state and that its full quality assurance system, according annex II excluding point 4 of the Directive 93/42/EEC, is approved (CE certificate n°8881 delivered by notified body GMED).

20109007	HELI-GIRO-FILES	P6 Heli-Giro-Files n025 L21 M07 ISO	P6 Heli-Giro-Files n025 L21 M07 ISO	Ila	2
20109008	HELI-GIRO-FILES	P6 Heli-Giro-Files n025 L25 M07 ISO	P6 Heli-Giro-Files n025 L25 M07 ISO	Ila	2
20109010	HELI-GIRO-FILES	P6 Heli-Giro-Files n030 L21 M07 ISO	P6 Heli-Giro-Files n030 L21 M07 ISO	Ila	2
20109011	HELI-GIRO-FILES	P6 Heli-Giro-Files n030 L25 M07 ISO	P6 Heli-Giro-Files n030 L25 M07 ISO	Ila	2
20109013	HELI-GIRO-FILES	P6 Heli-Giro-Files n035 L21 M07 ISO	P6 Heli-Giro-Files n035 L21 M07 ISO	Ila	2
20109014	HELI-GIRO-FILES	P6 Heli-Giro-Files n035 L25 M07 ISO	P6 Heli-Giro-Files n035 L25 M07 ISO	Ila	2
20109016	HELI-GIRO-FILES	P6 Heli-Giro-Files n040 L21 M07 ISO	P6 Heli-Giro-Files n040 L21 M07 ISO	Ila	2
20109017	HELI-GIRO-FILES	P6 Heli-Giro-Files n040 L25 M07 ISO	P6 Heli-Giro-Files n040 L25 M07 ISO	Ila	2
20109019	HELI-GIRO-FILES	P6 Heli-Giro-Files n045 L21 M07 ISO	P6 Heli-Giro-Files n045 L21 M07 ISO	Ila	2
20109020	HELI-GIRO-FILES	P6 Heli-Giro-Files n045 L25 M07 ISO	P6 Heli-Giro-Files n045 L25 M07 ISO	Ila	2
20109037	HELI-GIRO-FILES	P6 Heli-Giro-Files 015/040 L21 M07 ISO	P6 Heli-Giro-Files 015/040 L21 M07 ISO	Ila	2
20109038	HELI-GIRO-FILES	P6 Heli-Giro-Files 015/040 L25 M07 ISO	P6 Heli-Giro-Files 015/040 L25 M07 ISO	Ila	2
20136101	HERO 642	P6 HERO 642 n20 L25 2% Classics	P6 HERO 642 n20 L25 2% Classics	Ila	6
20136102	HERO 642	P6 HERO 642 n25 L25 2% Classics	P6 HERO 642 n25 L25 2% Classics	Ila	6
20136103	HERO 642	P6 HERO 642 n30 L25 2% Classics	P6 HERO 642 n30 L25 2% Classics	Ila	6
20136104	HERO 642	P6 HERO 642 n35 L25 2% Classics	P6 HERO 642 n35 L25 2% Classics	Ila	6
20136105	HERO 642	P6 HERO 642 n40 L25 2% Classics	P6 HERO 642 n40 L25 2% Classics	Ila	6
20136106	HERO 642	P6 HERO 642 n45 L25 2% Classics	P6 HERO 642 n45 L25 2% Classics	Ila	6
20136107	HERO 642	P6 HERO 642 n20 L25 4% Classics	P6 HERO 642 n20 L25 4% Classics	Ila	6
20136108	HERO 642	P6 HERO 642 n25 L25 4% Classics	P6 HERO 642 n25 L25 4% Classics	Ila	6
20136109	HERO 642	P6 HERO 642 n30 L25 4% Classics	P6 HERO 642 n30 L25 4% Classics	Ila	6
20136110	HERO 642	P6 HERO 642 n20 L21 6% Classics	P6 HERO 642 n20 L21 6% Classics	Ila	6
20136111	HERO 642	P6 HERO 642 n25 L21 6% Classics	P6 HERO 642 n25 L21 6% Classics	Ila	6
20136112	HERO 642	P6 HERO 642 n30 L21 6% Classics	P6 HERO 642 n30 L21 6% Classics	Ila	6
20136113	HERO 642	P9 HERO 642 Asst L21 6% L25 4% 2% Classics	P9 HERO 642 Asst L21 6% L25 4% 2% Classics	Ila	6
20136114	HERO 642	P6 HERO 642 n20 L21 2% Classics	P6 HERO 642 n20 L21 2% Classics	Ila	6
20136115	HERO 642	P6 HERO 642 n25 L21 2% Classics	P6 HERO 642 n25 L21 2% Classics	Ila	6
20136116	HERO 642	P6 HERO 642 n30 L21 2% Classics	P6 HERO 642 n30 L21 2% Classics	Ila	6
20136117	HERO 642	P6 HERO 642 n35 L21 2% Classics	P6 HERO 642 n35 L21 2% Classics	Ila	6
20136118	HERO 642	P6 HERO 642 n40 L21 2% Classics	P6 HERO 642 n40 L21 2% Classics	Ila	6
20136119	HERO 642	P6 HERO 642 n45 L21 2% Classics	P6 HERO 642 n45 L21 2% Classics	Ila	6
20136120	HERO 642	P6 HERO 642 n20 L21 4% Classics	P6 HERO 642 n20 L21 4% Classics	Ila	6
20136121	HERO 642	P6 HERO 642 n25 L21 4% Classics	P6 HERO 642 n25 L21 4% Classics	Ila	6
20136122	HERO 642	P6 HERO 642 n30 L21 4% Classics	P6 HERO 642 n30 L21 4% Classics	Ila	6
20136123	HERO 642	P6 HERO 642 n35 L29 2% Classics	P6 HERO 642 n35 L29 2% Classics	Ila	6
20136124	HERO 642	P6 HERO 642 n40 L29 2% Classics	P6 HERO 642 n40 L29 2% Classics	Ila	6
20136125	HERO 642	P6 HERO 642 n45 L29 2% Classics	P6 HERO 642 n45 L29 2% Classics	Ila	6
20136126	HERO 642	P6 HERO 642 n20 L29 2% Classics	P6 HERO 642 n20 L29 2% Classics	Ila	6
20136127	HERO 642	P6 HERO 642 n25 L29 2% Classics	P6 HERO 642 n25 L29 2% Classics	Ila	6
20136128	HERO 642	P6 HERO 642 n30 L29 2% Classics	P6 HERO 642 n30 L29 2% Classics	Ila	6
20136129	HERO 642	P6 HERO 642 n20 L29 4% Classics	P6 HERO 642 n20 L29 4% Classics	Ila	6
20136130	HERO 642	P6 HERO 642 n25 L29 4% Classics	P6 HERO 642 n25 L29 4% Classics	Ila	6
20136131	HERO 642	P6 HERO 642 n30 L29 4% Classics	P6 HERO 642 n30 L29 4% Classics	Ila	6
20136132	HERO 642	P6 HERO 642 n20 L25 6% Classics	P6 HERO 642 n20 L25 6% Classics	Ila	6
20136133	HERO 642	P6 HERO 642 n25 L25 6% Classics	P6 HERO 642 n25 L25 6% Classics	Ila	6
20136134	HERO 642	P6 HERO 642 n30 L25 6% Classics	P6 HERO 642 n30 L25 6% Classics	Ila	6
20136401	HERO Shaper	P6 HERO Shaper n20 L21 6% Classics	P6 HERO Shaper n20 L21 6% Classics	Ila	6
20136402	HERO Shaper	P6 HERO Shaper n25 L21 6% Classics	P6 HERO Shaper n25 L21 6% Classics	Ila	6
20136403	HERO Shaper	P6 HERO Shaper n30 L21 6% Classics	P6 HERO Shaper n30 L21 6% Classics	Ila	6
20136404	HERO Shaper	P6 HERO Shaper n20 L25 4% Classics	P6 HERO Shaper n20 L25 4% Classics	Ila	6
20136405	HERO Shaper	P6 HERO Shaper n25 L25 4% Classics	P6 HERO Shaper n25 L25 4% Classics	Ila	6
20136406	HERO Shaper	P6 HERO Shaper n30 L25 4% Classics	P6 HERO Shaper n30 L25 4% Classics	Ila	6
20136407	HERO Shaper	P6 HERO Shaper n20 L29 4% Classics	P6 HERO Shaper n20 L29 4% Classics	Ila	6
20136408	HERO Shaper	P6 HERO Shaper n25 L29 4% Classics	P6 HERO Shaper n25 L29 4% Classics	Ila	6
20136409	HERO Shaper	P6 HERO Shaper n30 L29 4% Classics	P6 HERO Shaper n30 L29 4% Classics	Ila	6
20136410	HERO Shaper	P6 HERO Shaper n20 L25 6% Classics	P6 HERO Shaper n20 L25 6% Classics	Ila	6
20136411	HERO Shaper	P6 HERO Shaper n25 L25 6% Classics	P6 HERO Shaper n25 L25 6% Classics	Ila	6

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA
Stéphane CLAUDE
Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

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20136412	HERO Shaper	P6 HERO Shaper n30 L25 6% Classics	P6 HERO Shaper n30 L25 6% Classics	Ila	6
20136413	HERO Shaper	P2 HERO Shaper canaux faciles Classics	P2 HERO Shaper Easy Canals Classics	Ila	6
20136414	HERO Shaper	P3 HERO Shaper canaux intermediaires Classics	P3 HERO Shaper Intermediate Canals Classics	Ila	6
20136415	HERO Shaper	P4 HERO Shaper canaux difficiles Classics	P4 HERO Shaper Difficult Canals Classics	Ila	6
20136416	HERO Shaper	P6 HERO Shaper Asst L21 6% L25 4%	P6 HERO Shaper Asst L21 6% L25 4%	Ila	6
20136417	HERO Shaper	P6 HERO Shaper n20 L21 4% Classics	P6 HERO Shaper n20 L21 4% Classics	Ila	6
20136418	HERO Shaper	P6 HERO Shaper n25 L21 4% Classics	P6 HERO Shaper n25 L21 4% Classics	Ila	6
20136419	HERO Shaper	P6 HERO Shaper n30 L21 4% Classics	P6 HERO Shaper n30 L21 4% Classics	Ila	6
20136420	HERO Shaper	P6 HERO Shaper n35 L25 4% Classics	P6 HERO Shaper n35 L25 4% Classics	Ila	6
20136421	HERO Shaper	P6 HERO Shaper n40 L25 4% Classics	P6 HERO Shaper n40 L25 4% Classics	Ila	6
20136422	HERO Shaper	P6 HERO Shaper n45 L25 4% Classics	P6 HERO Shaper n45 L25 4% Classics	Ila	6
20136423	HERO Shaper	P6 HERO Shaper n35 L21 4% Classics	P6 HERO Shaper n35 L21 4% Classics	Ila	6
20136424	HERO Shaper	P6 HERO Shaper n40 L21 4% Classics	P6 HERO Shaper n40 L21 4% Classics	Ila	6
20136425	HERO Shaper	P6 HERO Shaper n45 L21 4% Classics	P6 HERO Shaper n45 L21 4% Classics	Ila	6
20136426	HERO Shaper	P6 HERO Shaper n35 L29 4% Classics	P6 HERO Shaper n35 L29 4% Classics	Ila	6
20136427	HERO Shaper	P6 HERO Shaper n40 L29 4% Classics	P6 HERO Shaper n40 L29 4% Classics	Ila	6
20136428	HERO Shaper	P6 HERO Shaper n45 L29 4% Classics	P6 HERO Shaper n45 L29 4% Classics	Ila	6
20136429	HERO Shaper	P6 HERO Shaper Asst L21 6% 4% Classics	P6 HERO Shaper Asst L21 6% 4% Classics	Ila	6
20136430	HERO Shaper	P6 HERO Shaper Asst L25 6% 4% Classics	P6 HERO Shaper Asst L25 6% 4% Classics	Ila	6
20136701	HERO Shaper	P6 HERO Shaper n20 L21 6% InGeT	P6 HERO Shaper n20 L21 6% InGeT	Ila	6
20136702	HERO Shaper	P6 HERO Shaper n25 L21 6% InGeT	P6 HERO Shaper n25 L21 6% InGeT	Ila	6
20136703	HERO Shaper	P6 HERO Shaper n30 L21 6% InGeT	P6 HERO Shaper n30 L21 6% InGeT	Ila	6
20136704	HERO Shaper	P6 HERO Shaper n20 L25 4% InGeT	P6 HERO Shaper n20 L25 4% InGeT	Ila	6
20136705	HERO Shaper	P6 HERO Shaper n25 L25 4% InGeT	P6 HERO Shaper n25 L25 4% InGeT	Ila	6
20136706	HERO Shaper	P6 HERO Shaper n30 L25 4% InGeT	P6 HERO Shaper n30 L25 4% InGeT	Ila	6
20136707	HERO Shaper	P6 HERO Shaper n20 L29 4% InGeT	P6 HERO Shaper n20 L29 4% InGeT	Ila	6
20136708	HERO Shaper	P6 HERO Shaper n25 L29 4% InGeT	P6 HERO Shaper n25 L29 4% InGeT	Ila	6
20136709	HERO Shaper	P6 HERO Shaper n30 L29 4% InGeT	P6 HERO Shaper n30 L29 4% InGeT	Ila	6
20136710	HERO Shaper	P6 HERO Shaper n20 L25 6% InGeT	P6 HERO Shaper n20 L25 6% InGeT	Ila	6
20136711	HERO Shaper	P6 HERO Shaper n25 L25 6% InGeT	P6 HERO Shaper n25 L25 6% InGeT	Ila	6
20136712	HERO Shaper	P6 HERO Shaper n30 L25 6% InGeT	P6 HERO Shaper n30 L25 6% InGeT	Ila	6
20136713	HERO Shaper	P6 HERO Shaper n20 L21 4% InGeT	P6 HERO Shaper n20 L21 4% InGeT	Ila	6
20136714	HERO Shaper	P6 HERO Shaper n25 L21 4% InGeT	P6 HERO Shaper n25 L21 4% InGeT	Ila	6
20136715	HERO Shaper	P6 HERO Shaper n30 L21 4% InGeT	P6 HERO Shaper n30 L21 4% InGeT	Ila	6
20136716	HERO Shaper	P6 HERO Shaper Asst L21 6% L25 4% InGeT	P6 HERO Shaper Asst L21 6% L25 4% InGeT	Ila	6
20136720	HERO Shaper	P2 HERO Shaper Canaux Faciles InGeT	P2 HERO Shaper Easy Canals InGeT	Ila	6
20136721	HERO Shaper	P3 HERO Shaper Canaux Intermediaires InGeT	P3 HERO Shaper Intermediate Canals InGeT	Ila	6
20136722	HERO Shaper	P4 HERO Shaper Canaux Difficiles InGeT	P4 HERO Shaper Difficult Canals InGeT	Ila	6
20136723	HERO Shaper	P6 HERO Shaper n35 L25 4% InGeT	P6 HERO Shaper n35 L25 4% InGeT	Ila	6
20136724	HERO Shaper	P6 HERO Shaper n40 L25 4% InGeT	P6 HERO Shaper n40 L25 4% InGeT	Ila	6
20136725	HERO Shaper	P6 HERO Shaper n45 L25 4% InGeT	P6 HERO Shaper n45 L25 4% InGeT	Ila	6
20136726	HERO Shaper	P6 HERO Shaper n35 L21 4% InGeT	P6 HERO Shaper n35 L21 4% InGeT	Ila	6
20136727	HERO Shaper	P6 HERO Shaper n40 L21 4% InGeT	P6 HERO Shaper n40 L21 4% InGeT	Ila	6
20136728	HERO Shaper	P6 HERO Shaper n45 L21 4% InGeT	P6 HERO Shaper n45 L21 4% InGeT	Ila	6
20136729	HERO Shaper	P6 HERO Shaper n35 L29 4% InGeT	P6 HERO Shaper n35 L29 4% InGeT	Ila	6
20136730	HERO Shaper	P6 HERO Shaper n40 L29 4% InGeT	P6 HERO Shaper n40 L29 4% InGeT	Ila	6
20136731	HERO Shaper	P6 HERO Shaper n45 L29 4% InGeT	P6 HERO Shaper n45 L29 4% InGeT	Ila	6
20136733	HERO Shaper	P6 HERO Shaper Asst L25 6% 4% InGeT	P6 HERO Shaper Asst L25 6% 4% InGeT	Ila	6
20936401	HERO Shaper	B5 HERO Shaper n020 L21 6% Classics Sterile	B5 HERO Shaper n020 L21 6% Classics Sterile	Ila	6
20936402	HERO Shaper	B5 HERO Shaper n025 L21 6% Classics Sterile	B5 HERO Shaper n025 L21 6% Classics Sterile	Ila	6
20936403	HERO Shaper	B5 HERO Shaper n030 L21 6% Classics Sterile	B5 HERO Shaper n030 L21 6% Classics Sterile	Ila	6
20936404	HERO Shaper	B5 HERO Shaper n020 L25 4% Classics Sterile	B5 HERO Shaper n020 L25 4% Classics Sterile	Ila	6
20936405	HERO Shaper	B5 HERO Shaper n025 L25 4% Classics Sterile	B5 HERO Shaper n025 L25 4% Classics Sterile	Ila	6
20936406	HERO Shaper	B5 HERO Shaper n030 L25 4% Classics Sterile	B5 HERO Shaper n030 L25 4% Classics Sterile	Ila	6
20936407	HERO Shaper	B5 HERO Shaper n020 L29 4% Classics Sterile	B5 HERO Shaper n020 L29 4% Classics Sterile	Ila	6
20936408	HERO Shaper	B5 HERO Shaper n025 L29 4% Classics Sterile	B5 HERO Shaper n025 L29 4% Classics Sterile	Ila	6
20936409	HERO Shaper	B5 HERO Shaper n030 L29 4% Classics Sterile	B5 HERO Shaper n030 L29 4% Classics Sterile	Ila	6

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA

Stéphane CLAUDE

Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

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20936410	HERO Shaper	B5 HERO Shaper n020 L25 6% Classics Sterile	B5 HERO Shaper n020 L25 6% Classics Sterile	Ila	6
20936411	HERO Shaper	B5 HERO Shaper n025 L25 6% Classics Sterile	B5 HERO Shaper n025 L25 6% Classics Sterile	Ila	6
20936412	HERO Shaper	B5 HERO Shaper n030 L25 6% Classics Sterile	B5 HERO Shaper n030 L25 6% Classics Sterile	Ila	6
20936417	HERO Shaper	B5 HERO Shaper n020 L21 4% Classics Sterile	B5 HERO Shaper n020 L21 4% Classics Sterile	Ila	6
20936418	HERO Shaper	B5 HERO Shaper n025 L21 4% Classics Sterile	B5 HERO Shaper n025 L21 4% Classics Sterile	Ila	6
20936419	HERO Shaper	B5 HERO Shaper n030 L21 4% Classics Sterile	B5 HERO Shaper n030 L21 4% Classics Sterile	Ila	6
20936420	HERO Shaper	B5 HERO Shaper n035 L25 4% Classics Sterile	B5 HERO Shaper n035 L25 4% Classics Sterile	Ila	6
20936421	HERO Shaper	B5 HERO Shaper n040 L25 4% Classics Sterile	B5 HERO Shaper n040 L25 4% Classics Sterile	Ila	6
20936422	HERO Shaper	B5 HERO Shaper n045 L25 4% Classics Sterile	B5 HERO Shaper n045 L25 4% Classics Sterile	Ila	6
20936423	HERO Shaper	B5 HERO Shaper n035 L21 4% Classics Sterile	B5 HERO Shaper n035 L21 4% Classics Sterile	Ila	6
20936424	HERO Shaper	B5 HERO Shaper n040 L21 4% Classics Sterile	B5 HERO Shaper n040 L21 4% Classics Sterile	Ila	6
20936425	HERO Shaper	B5 HERO Shaper n045 L21 4% Classics Sterile	B5 HERO Shaper n045 L21 4% Classics Sterile	Ila	6
20936426	HERO Shaper	B5 HERO Shaper n035 L29 4% Classics Sterile	B5 HERO Shaper n035 L29 4% Classics Sterile	Ila	6
20936427	HERO Shaper	B5 HERO Shaper n040 L29 4% Classics Sterile	B5 HERO Shaper n040 L29 4% Classics Sterile	Ila	6
20936428	HERO Shaper	B5 HERO Shaper n045 L29 4% Classics Sterile	B5 HERO Shaper n045 L29 4% Classics Sterile	Ila	6
20120002	MECA-RISPI	P6 Meca-Rispi n0 L21 ISO M11	P6 Meca-Rispi n0 L21 ISO M11	Ila	3
20120003	MECA-RISPI	P6 Meca-Rispi n0 L25 ISO M11	P6 Meca-Rispi n0 L25 ISO M11	Ila	3
20120006	MECA-RISPI	P6 Meca-Rispi n1 L21 ISO M11	P6 Meca-Rispi n1 L21 ISO M11	Ila	3
20120007	MECA-RISPI	P6 Meca-Rispi n1 L25 ISO M11	P6 Meca-Rispi n1 L25 ISO M11	Ila	3
20120010	MECA-RISPI	P6 Meca-Rispi n2 L21 ISO M11	P6 Meca-Rispi n2 L21 ISO M11	Ila	3
20120011	MECA-RISPI	P6 Meca-Rispi n2 L25 ISO M11	P6 Meca-Rispi n2 L25 ISO M11	Ila	3
20120014	MECA-RISPI	P6 Meca-Rispi n3 L21 ISO M11	P6 Meca-Rispi n3 L21 ISO M11	Ila	3
20120015	MECA-RISPI	P6 Meca-Rispi n3 L25 ISO M11	P6 Meca-Rispi n3 L25 ISO M11	Ila	3
20120018	MECA-RISPI	P6 Meca-Rispi n4 L21 ISO M11	P6 Meca-Rispi n4 L21 ISO M11	Ila	3
20120019	MECA-RISPI	P6 Meca-Rispi n4 L25 ISO M11	P6 Meca-Rispi n4 L25 ISO M11	Ila	3
20120022	MECA-RISPI	P6 Meca-Rispi n5 L21 ISO M11	P6 Meca-Rispi n5 L21 ISO M11	Ila	3
20120023	MECA-RISPI	P6 Meca-Rispi n5 L25 ISO M11	P6 Meca-Rispi n5 L25 ISO M11	Ila	3
20120026	MECA-RISPI	P6 Meca-Rispi n6 L21 ISO M11	P6 Meca-Rispi n6 L21 ISO M11	Ila	3
20120027	MECA-RISPI	P6 Meca-Rispi n6 L25 ISO M11	P6 Meca-Rispi n6 L25 ISO M11	Ila	3
20120031	MECA-RISPI	P6 Meca-Rispi 1/6 L25 ISO M11	P6 Meca-Rispi 1/6 L25 ISO M11	Ila	3
20119003	MECA-SHAPER	P6 Meca-Shaper n10 L25 ISO M11	P6 Meca-Shaper n10 L25 ISO M11	Ila	3
20119006	MECA-SHAPER	P6 Meca-Shaper n15 L21 ISO M11	P6 Meca-Shaper n15 L21 ISO M11	Ila	3
20119007	MECA-SHAPER	P6 Meca-Shaper n15 L25 ISO M11	P6 Meca-Shaper n15 L25 ISO M11	Ila	3
20119010	MECA-SHAPER	P6 Meca-Shaper n20 L21 ISO M11	P6 Meca-Shaper n20 L21 ISO M11	Ila	3
20119011	MECA-SHAPER	P6 Meca-Shaper n20 L25 ISO M11	P6 Meca-Shaper n20 L25 ISO M11	Ila	3
20119014	MECA-SHAPER	P6 Meca-Shaper n25 L21 ISO M11	P6 Meca-Shaper n25 L21 ISO M11	Ila	3
20119015	MECA-SHAPER	P6 Meca-Shaper n25 L25 ISO M11	P6 Meca-Shaper n25 L25 ISO M11	Ila	3
20119018	MECA-SHAPER	P6 Meca-Shaper n30 L21 ISO M11	P6 Meca-Shaper n30 L21 ISO M11	Ila	3
20119019	MECA-SHAPER	P6 Meca-Shaper n30 L25 ISO M11	P6 Meca-Shaper n30 L25 ISO M11	Ila	3
20119022	MECA-SHAPER	P6 Meca-Shaper n35 L21 ISO M11	P6 Meca-Shaper n35 L21 ISO M11	Ila	3
20119023	MECA-SHAPER	P6 Meca-Shaper n35 L25 ISO M11	P6 Meca-Shaper n35 L25 ISO M11	Ila	3
20119026	MECA-SHAPER	P6 Meca-Shaper n40 L21 ISO M11	P6 Meca-Shaper n40 L21 ISO M11	Ila	3
20119027	MECA-SHAPER	P6 Meca-Shaper n40 L25 ISO M11	P6 Meca-Shaper n40 L25 ISO M11	Ila	3
20119030	MECA-SHAPER	P6 Meca-Shaper 15/40 L21 ISO M11	P6 Meca-Shaper 15/40 L21 ISO M11	Ila	3
20119031	MECA-SHAPER	P6 Meca-Shaper 15/40 L25 ISO M11	P6 Meca-Shaper 15/40 L25 ISO M11	Ila	3
20149401	ONE CURVE	P3 ONE CURVE n25 6% L21	P3 ONE CURVE n25 6% L21	Ila	6
20149402	ONE CURVE	P3 ONE CURVE n25 6% L25	P3 ONE CURVE n25 6% L25	Ila	6
20149403	ONE CURVE	P3 ONE CURVE n25 6% L31	P3 ONE CURVE n25 6% L31	Ila	6
20149411	ONE CURVE	P6 ONE CURVE n25 6% L21	P6 ONE CURVE n25 6% L21	Ila	6
20149412	ONE CURVE	P6 ONE CURVE n25 6% L25	P6 ONE CURVE n25 6% L25	Ila	6
20149413	ONE CURVE	P6 ONE CURVE n25 6% L31	P6 ONE CURVE n25 6% L31	Ila	6
20949401	ONE CURVE	B5 ONE CURVE n25 6% L21 Sterile	B5 ONE CURVE n25 6% L21 Sterile	Ila	6
20949402	ONE CURVE	B5 ONE CURVE n25 6% L25 Sterile	B5 ONE CURVE n25 6% L25 Sterile	Ila	6
20949403	ONE CURVE	B5 ONE CURVE n25 6% L31 Sterile	B5 ONE CURVE n25 6% L31 Sterile	Ila	6
20949411	ONE CURVE	B5 ONE CURVE n25 6% L21 PROCEDURE PACK Sterile	B5 ONE CURVE n25 6% L21 PROCEDURE PACK Sterile	Ila	6
20949412	ONE CURVE	B5 ONE CURVE n25 6% L25 PROCEDURE PACK Sterile	B5 ONE CURVE n25 6% L25 PROCEDURE PACK Sterile	Ila	6
20949413	ONE CURVE	B5 ONE CURVE n25 6% L31 PROCEDURE PACK Sterile	B5 ONE CURVE n25 6% L31 PROCEDURE PACK Sterile	Ila	6

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA
Stéphane CLAUDE
Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

Micro-Mega SA
12 rue du Tunnel
25000 BESANCON
France

GMED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits le 12 mai 2021

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed on May 12, 2021

COLTENE
MicroMega

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

Micro-Mega SA certifie que les produits suivants sont conformes à l'annexe I et VII de la directive 93/42 CEE relative aux dispositifs médicaux, en tenant compte de toutes les normes harmonisées européennes applicables et aux transpositions en droit national de chaque état et que son système d'assurance qualité, selon l'annexe II excluant le point 4 de la directive 93/42 CEE, est approuvé (Attestation CE n°8881 délivrée par l'organisme notifié GMED).

Micro-Mega SA certifies that the products listed below conform to annex I and VII of the Directive 93/42/EEC for medical devices, taking into account all applicable European harmonised standards and national laws for each state and that it full quality assurance system, according annex II excluding point 4 of the Directive 93/42/EEC, is approved (CE certificate n°8881 delivered by notified body GMED).

20949421	ONE CURVE	B4 ONE CURVE n25 6% L21 STARTER PACK Sterile	B4 ONE CURVE n25 6% L21 STARTER PACK Sterile	Ila	6
20949422	ONE CURVE	B4 ONE CURVE n25 6% L25 STARTER PACK Sterile	B4 ONE CURVE n25 6% L25 STARTER PACK Sterile	Ila	6
20949423	ONE CURVE	B4 ONE CURVE n25 6% L31 STARTER PACK Sterile	B4 ONE CURVE n25 6% L31 STARTER PACK Sterile	Ila	6
20952201	ONE FLARE	B5 ONE FLARE n25 9% L17 Classics sterile	B5 ONE FLARE n25 9% L17 Classics sterile	Ila	6
20948201	ONE G	B5 ONE G n014 3% L21 Classics Sterile	B5 ONE G n014 3% L21 Classics Sterile	Ila	6
20948202	ONE G	B5 ONE G n014 3% L25 Classics Sterile	B5 ONE G n014 3% L25 Classics Sterile	Ila	6
20948203	ONE G	B5 ONE G n014 3% L29 Classics Sterile	B5 ONE G n014 3% L29 Classics Sterile	Ila	6
20949001	ONE SHAPE	B5 ONE SHAPE n025 L21 6% Classics	B5 ONE SHAPE n025 L21 6% Classics	Ila	6
20949002	ONE SHAPE	B5 ONE SHAPE n025 L25 6% Classics	B5 ONE SHAPE n025 L25 6% Classics	Ila	6
20949003	ONE SHAPE	B5 ONE SHAPE n025 L29 6% Classics	B5 ONE SHAPE n025 L29 6% Classics	Ila	6
20949201	ONE SHAPE APICAL	B5 ONE SHAPE APICAL1 n030 6% L21 Classics sterile	B5 ONE SHAPE APICAL1 n030 6% L21 Classics sterile	Ila	6
20949202	ONE SHAPE APICAL	B5 ONE SHAPE APICAL1 n030 6% L25 Classics sterile	B5 ONE SHAPE APICAL1 n030 6% L25 Classics sterile	Ila	6
20949203	ONE SHAPE APICAL	B5 ONE SHAPE APICAL1 n030 6% L29 Classics sterile	B5 ONE SHAPE APICAL1 n030 6% L29 Classics sterile	Ila	6
20949211	ONE SHAPE APICAL	B5 ONE SHAPE APICAL2 n037 6% L21 Classics sterile	B5 ONE SHAPE APICAL2 n037 6% L21 Classics sterile	Ila	6
20949212	ONE SHAPE APICAL	B5 ONE SHAPE APICAL2 n037 6% L25 Classics sterile	B5 ONE SHAPE APICAL2 n037 6% L25 Classics sterile	Ila	6
20949213	ONE SHAPE APICAL	B5 ONE SHAPE APICAL2 n037 6% L29 Classics sterile	B5 ONE SHAPE APICAL2 n037 6% L29 Classics sterile	Ila	6
20121002	PASTINJECT	P4 Pastinject n15 L21 ISO M07	P4 Pastinject n15 L21 ISO M07	Ila	10
20121003	PASTINJECT	P4 Pastinject n15 L25 ISO M07	P4 Pastinject n15 L25 ISO M07	Ila	10
20121004	PASTINJECT	P4 Pastinject n15 L29 ISO M07	P4 Pastinject n15 L29 ISO M07	Ila	10
20121006	PASTINJECT	P4 Pastinject n20 L21 ISO M07	P4 Pastinject n20 L21 ISO M07	Ila	10
20121007	PASTINJECT	P4 Pastinject n20 L25 ISO M07	P4 Pastinject n20 L25 ISO M07	Ila	10
20121008	PASTINJECT	P4 Pastinject n20 L29 ISO M07	P4 Pastinject n20 L29 ISO M07	Ila	10
20121010	PASTINJECT	P4 Pastinject n25 L21 ISO M07	P4 Pastinject n25 L21 ISO M07	Ila	10
20121011	PASTINJECT	P4 Pastinject n25 L25 ISO M07	P4 Pastinject n25 L25 ISO M07	Ila	10
20121012	PASTINJECT	P4 Pastinject n25 L29 ISO M07	P4 Pastinject n25 L29 ISO M07	Ila	10
20121014	PASTINJECT	P4 Pastinject n30 L21 ISO M07	P4 Pastinject n30 L21 ISO M07	Ila	10
20121015	PASTINJECT	P4 Pastinject n30 L25 ISO M07	P4 Pastinject n30 L25 ISO M07	Ila	10
20121016	PASTINJECT	P4 Pastinject n30 L29 ISO M07	P4 Pastinject n30 L29 ISO M07	Ila	10
20121018	PASTINJECT	P4 Pastinject n35 L21 ISO M07	P4 Pastinject n35 L21 ISO M07	Ila	10
20121019	PASTINJECT	P4 Pastinject n35 L25 ISO M07	P4 Pastinject n35 L25 ISO M07	Ila	10
20121020	PASTINJECT	P4 Pastinject n35 L29 ISO M07	P4 Pastinject n35 L29 ISO M07	Ila	10
20121022	PASTINJECT	P4 Pastinject 25/40 L21 ISO M07	P4 Pastinject 25/40 L21 ISO M07	Ila	10
20121023	PASTINJECT	P4 Pastinject 25/40 L25 ISO M07	P4 Pastinject 25/40 L25 ISO M07	Ila	10
20121024	PASTINJECT	P4 Pastinject 25/40 L29 ISO M07	P4 Pastinject 25/40 L29 ISO M07	Ila	10
20121026	PASTINJECT	P4 Pastinject n40 L21 ISO M07	P4 Pastinject n40 L21 ISO M07	Ila	10
20121027	PASTINJECT	P4 Pastinject n40 L25 ISO M07	P4 Pastinject n40 L25 ISO M07	Ila	10
20121028	PASTINJECT	P4 Pastinject n40 L29 ISO M07	P4 Pastinject n40 L29 ISO M07	Ila	10
20921006	PASTINJECT	B5 Pastinject n020 L21 M07 stérile	B5 Pastinject n020 L21 M07 stérile	Ila	10
20921007	PASTINJECT	B5 Pastinject n020 L25 M07 stérile	B5 Pastinject n020 L25 M07 stérile	Ila	10
20921010	PASTINJECT	B5 Pastinject n025 L21 M07 stérile	B5 Pastinject n025 L21 M07 stérile	Ila	10
20921011	PASTINJECT	B5 Pastinject n025 L25 M07 stérile	B5 Pastinject n025 L25 M07 stérile	Ila	10
20921014	PASTINJECT	B5 Pastinject n030 L21 M07 stérile	B5 Pastinject n030 L21 M07 stérile	Ila	10
20921015	PASTINJECT	B5 Pastinject n030 L25 M07 stérile	B5 Pastinject n030 L25 M07 stérile	Ila	10
20921018	PASTINJECT	B5 Pastinject n035 L21 M07 stérile	B5 Pastinject n035 L21 M07 stérile	Ila	10
20921019	PASTINJECT	B5 Pastinject n035 L25 M07 stérile	B5 Pastinject n035 L25 M07 stérile	Ila	10
20921026	PASTINJECT	B5 Pastinject n040 L21 M07 stérile	B5 Pastinject n040 L21 M07 stérile	Ila	10
20921027	PASTINJECT	B5 Pastinject n040 L25 M07 stérile	B5 Pastinject n040 L25 M07 stérile	Ila	10
20949301	PROCEDURE PACK	B5 ONE SHAPE Procedure Pack L21 Classics Sterile	B5 ONE SHAPE Procedure Pack L21 Classics Sterile	Ila	6
20949302	PROCEDURE PACK	B5 ONE SHAPE Procedure Pack L25 Classics Sterile	B5 ONE SHAPE Procedure Pack L25 Classics Sterile	Ila	6
20949303	PROCEDURE PACK	B5 ONE SHAPE Procedure Pack L29 Classics Sterile	B5 ONE SHAPE Procedure Pack L29 Classics Sterile	Ila	6
20142001	R-ENDO	P6 R-Endo Re InGeT	P6 R-Endo Re InGeT	Ila	6
20142002	R-ENDO	P6 R-Endo R1 InGeT	P6 R-Endo R1 InGeT	Ila	6
20142003	R-ENDO	P6 R-Endo R2 InGeT	P6 R-Endo R2 InGeT	Ila	6
20142004	R-ENDO	P6 R-Endo R3 InGeT	P6 R-Endo R3 InGeT	Ila	6
20142006	R-ENDO	P5 R-Endo series InGeT Re-R1-R2-R3-Rs	P5 R-Endo series InGeT Re-R1-R2-R3-Rs	Ila	6
20142007	R-ENDO	P6 R-Endo Rs InGeT	P6 R-Endo Rs InGeT	Ila	6
20142201	R-ENDO	P6 R-Endo Re Classics	P6 R-Endo Re Classics	Ila	6

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA
Stéphane CLAUDE
Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

Micro-Mega SA
12 rue du Tunnel
25000 BESANCON
France

GMED (0459) reconnait que son certificat CE est valide pour
les dispositifs médicaux décrits le 12 mai 2021

GMED (0459) recognizes that its EC certificate is valid for the
medical devices listed on May 12, 2021

COLTENE
MicroMega

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

Micro-Mega SA certifie que les produits suivants sont conformes à l'annexe I et VII de la directive 93/42 CEE relative aux dispositifs médicaux, en tenant compte de toutes les normes harmonisées européennes applicables et aux transpositions en droit national de chaque état et que son système d'assurance qualité, selon l'annexe II excluant le point 4 de la directive 93/42 CEE, est approuvé (Attestation CE n°8881 délivrée par l'organisme notifié GMED).

Micro-Mega SA certifies that the products listed below conform to annex I and VII of the Directive 93/42/EEC for medical devices, taking into account all applicable European harmonised standards and national laws for each state and that its full quality assurance system, according to annex II excluding point 4 of the Directive 93/42/EEC, is approved (CE certificate n°8881 delivered by notified body GMED).

20142202	R-ENDO	P6 R-Endo R1 Classics	P6 R-Endo R1 Classics	Ila	6
20142203	R-ENDO	P6 R-Endo R2 Classics	P6 R-Endo R2 Classics	Ila	6
20142204	R-ENDO	P6 R-Endo R3 Classics	P6 R-Endo R3 Classics	Ila	6
20142206	R-ENDO	P3 R-Endo Asst R1-R2-R3 Classics	P3 R-Endo Asst R1-R2-R3 Classics	Ila	6
20942201	R-ENDO	B5 R-Endo RE Classics stérile	B5 R-Endo RE Classics stérile	Ila	6
20942202	R-ENDO	B5 R-Endo R1 Classics stérile	B5 R-Endo R1 Classics stérile	Ila	6
20942203	R-ENDO	B5 R-Endo R2 Classics stérile	B5 R-Endo R2 Classics stérile	Ila	6
20942204	R-ENDO	B5 R-Endo R3 Classics stérile	B5 R-Endo R3 Classics stérile	Ila	6
20137701	REVO CONDENSOR	P4 Revo Condensor NITI n30 L25 4% Classics	P4 Revo Condensor NITI n30 L25 4% Classics	Ila	10
20137702	REVO CONDENSOR	P4 Revo Condensor NITI n30 L29 4% Classics	P4 Revo Condensor NITI n30 L29 4% Classics	Ila	10
20143111	REVO-S	P6 Revo-S series L25 L21 Classics	P6 Revo-S series L25 L21 Classics	Ila	6
20143112	REVO-S	P6 Revo-S series L29 L21 Classics	P6 Revo-S series L29 L21 Classics	Ila	6
20143113	REVO-S	P6 Revo-S series L21 Classics	P6 Revo-S series L21 Classics	Ila	6
20143115	REVO-S	P3 Revo-S SC1 SC2 SU Asst L25 L21 Classics	P3 Revo-S SC1 SC2 SU Asst L25 L21 Classics	Ila	6
20143116	REVO-S	P3 Revo-S SC1 SC2 SU Asst L29 L21 Classics	P3 Revo-S SC1 SC2 SU Asst L29 L21 Classics	Ila	6
20143117	REVO-S	P3 Revo-S SC1 SC2 SU Asst L21 Classics	P3 Revo-S SC1 SC2 SU Asst L21 Classics	Ila	6
20143120	REVO-S	P3 Revo-S AS30 AS35 AS40 Asst L25 Classics	P3 Revo-S AS30 AS35 AS40 Asst L25 Classics	Ila	6
20143121	REVO-S	P3 Revo-S AS30 AS35 AS40 Asst L29 Classics	P3 Revo-S AS30 AS35 AS40 Asst L29 Classics	Ila	6
20143122	REVO-S	P3 Revo-S AS30 AS35 AS40 Asst L21 Classics	P3 Revo-S AS30 AS35 AS40 Asst L21 Classics	Ila	6
20143151	REVO-S	P6 Revo-S SC1 n25 L21 6% Classics	P6 Revo-S SC1 n25 L21 6% Classics	Ila	6
20143155	REVO-S	P6 Revo-S SC2 n25 L25 4% Classics	P6 Revo-S SC2 n25 L25 4% Classics	Ila	6
20143156	REVO-S	P6 Revo-S SC2 n25 L29 4% Classics	P6 Revo-S SC2 n25 L29 4% Classics	Ila	6
20143157	REVO-S	P6 Revo-S SC2 n25 L21 4% Classics	P6 Revo-S SC2 n25 L21 4% Classics	Ila	6
20143160	REVO-S	P6 Revo-S SU n25 L25 6% Classics	P6 Revo-S SU n25 L25 6% Classics	Ila	6
20143161	REVO-S	P6 Revo-S SU n25 L29 6% Classics	P6 Revo-S SU n25 L29 6% Classics	Ila	6
20143162	REVO-S	P6 Revo-S SU n25 L21 6% Classics	P6 Revo-S SU n25 L21 6% Classics	Ila	6
20143170	REVO-S	P6 Revo-S AS30 L25 6% Classics	P6 Revo-S AS30 L25 6% Classics	Ila	6
20143171	REVO-S	P6 Revo-S AS30 L29 6% Classics	P6 Revo-S AS30 L29 6% Classics	Ila	6
20143172	REVO-S	P6 Revo-S AS30 L21 6% Classics	P6 Revo-S AS30 L21 6% Classics	Ila	6
20143175	REVO-S	P6 Revo-S AS35 L25 6% Classics	P6 Revo-S AS35 L25 6% Classics	Ila	6
20143176	REVO-S	P6 Revo-S AS35 L29 6% Classics	P6 Revo-S AS35 L29 6% Classics	Ila	6
20143177	REVO-S	P6 Revo-S AS35 L21 6% Classics	P6 Revo-S AS35 L21 6% Classics	Ila	6
20143180	REVO-S	P6 Revo-S AS40 L25 6% Classics	P6 Revo-S AS40 L25 6% Classics	Ila	6
20143181	REVO-S	P6 Revo-S AS40 L29 6% Classics	P6 Revo-S AS40 L29 6% Classics	Ila	6
20143182	REVO-S	P6 Revo-S AS40 L21 6% Classics	P6 Revo-S AS40 L21 6% Classics	Ila	6
20143211	REVO-S	P6 Revo-S series L25 L21 InGeT	P6 Revo-S series L25 L21 InGeT	Ila	6
20143212	REVO-S	P6 Revo-S series L29 L21 InGeT	P6 Revo-S series L29 L21 InGeT	Ila	6
20143215	REVO-S	P3 Revo-S SC1 SC2 SU Asst L25 L21 InGeT	P3 Revo-S SC1 SC2 SU Asst L25 L21 InGeT	Ila	6
20143216	REVO-S	P3 Revo-S SC1 SC2 SU Asst L29 L21 InGeT	P3 Revo-S SC1 SC2 SU Asst L29 L21 InGeT	Ila	6
20143220	REVO-S	P3 Revo-S AS30 AS35 AS40 Asst L25 InGeT	P3 Revo-S AS30 AS35 AS40 Asst L25 InGeT	Ila	6
20143221	REVO-S	P3 Revo-S AS30 AS35 AS40 Asst L29 InGeT	P3 Revo-S AS30 AS35 AS40 Asst L29 InGeT	Ila	6
20143251	REVO-S	P6 Revo-S SC1 n25 L21 6% InGeT	P6 Revo-S SC1 n25 L21 6% InGeT	Ila	6
20143255	REVO-S	P6 Revo-S SC2 n25 L25 4% InGeT	P6 Revo-S SC2 n25 L25 4% InGeT	Ila	6
20143256	REVO-S	P6 Revo-S SC2 n25 L29 4% InGeT	P6 Revo-S SC2 n25 L29 4% InGeT	Ila	6
20143260	REVO-S	P6 Revo-S SU n25 L25 6% InGeT	P6 Revo-S SU n25 L25 6% InGeT	Ila	6
20143261	REVO-S	P6 Revo-S SU n25 L29 6% InGeT	P6 Revo-S SU n25 L29 6% InGeT	Ila	6
20143270	REVO-S	P6 Revo-S AS30 L25 6% InGeT	P6 Revo-S AS30 L25 6% InGeT	Ila	6
20143271	REVO-S	P6 Revo-S AS30 L29 6% InGeT	P6 Revo-S AS30 L29 6% InGeT	Ila	6
20143275	REVO-S	P6 Revo-S AS35 L25 6% InGeT	P6 Revo-S AS35 L25 6% InGeT	Ila	6
20143276	REVO-S	P6 Revo-S AS35 L29 6% InGeT	P6 Revo-S AS35 L29 6% InGeT	Ila	6
20143280	REVO-S	P6 Revo-S AS40 L25 6% InGeT	P6 Revo-S AS40 L25 6% InGeT	Ila	6
20143281	REVO-S	P6 Revo-S AS40 L29 6% InGeT	P6 Revo-S AS40 L29 6% InGeT	Ila	6
20943151	REVO-S	B5 Revo-S SC1 L21 Classics stérile	B5 Revo-S SC1 L21 Classics stérile	Ila	6
20943155	REVO-S	B5 Revo-S SC2 L25 Classics stérile	B5 Revo-S SC2 L25 Classics stérile	Ila	6
20943156	REVO-S	B5 Revo-S SC2 L29 Classics stérile	B5 Revo-S SC2 L29 Classics stérile	Ila	6
20943157	REVO-S	B5 Revo-S SC2 L21 Classics stérile	B5 Revo-S SC2 L21 Classics stérile	Ila	6
20943160	REVO-S	B5 Revo-S SU L 25 Classics stérile	B5 Revo-S SU L 25 Classics stérile	Ila	6

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA

Stéphane CLAUDE

Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

Micro-Mega SA certifie que les produits suivants sont conformes à l'annexe I et VII de la directive 93/42 CEE relative aux dispositifs médicaux, en tenant compte de toutes les normes harmonisées européennes applicables et aux transpositions en droit national de chaque état et que son système d'assurance qualité, selon l'annexe II excluant le point 4 de la directive 93/42 CEE, est approuvé (Attestation CE n°8881 délivrée par l'organisme notifié GMED).

Micro-Mega SA certifies that the products listed below conform to annex I and VII of the Directive 93/42/EEC for medical devices, taking into account all applicable European harmonised standards and national laws for each state and that its full quality assurance system, according annex II excluding point 4 of the Directive 93/42/EEC, is approved (CE certificate n°8881 delivered by notified body GMED).

20943161	REVO-S	B5 Revo-S SU L29 Classics sterile	B5 Revo-S SU L29 Classics sterile	Ila	6
20943162	REVO-S	B5 Revo-S SU L21 Classics sterile	B5 Revo-S SU L21 Classics sterile	Ila	6
20943170	REVO-S	B5 Revo-S AS30 L25 Classics sterile	B5 Revo-S AS30 L25 Classics sterile	Ila	6
20943171	REVO-S	B5 Revo-S AS30 L29 Classics sterile	B5 Revo-S AS30 L29 Classics sterile	Ila	6
20943172	REVO-S	B5 Revo-S AS30 L21 Classics sterile	B5 Revo-S AS30 L21 Classics sterile	Ila	6
20943175	REVO-S	B5 Revo-S AS35 L25 Classics sterile	B5 Revo-S AS35 L25 Classics sterile	Ila	6
20943176	REVO-S	B5 Revo-S AS35 L29 Classics sterile	B5 Revo-S AS35 L29 Classics sterile	Ila	6
20943177	REVO-S	B5 Revo-S AS35 L21 Classics sterile	B5 Revo-S AS35 L21 Classics sterile	Ila	6
20943180	REVO-S	B5 Revo-S AS40 L25 Classics sterile	B5 Revo-S AS40 L25 Classics sterile	Ila	6
20943181	REVO-S	B5 Revo-S AS40 L29 Classics sterile	B5 Revo-S AS40 L29 Classics sterile	Ila	6
20943182	REVO-S	B5 Revo-S AS40 L21 Classics sterile	B5 Revo-S AS40 L21 Classics sterile	Ila	6
20116001	RISPI	P6 Rispi n0 L19 ISO M07	P6 Rispi n0 L19 ISO M07	Ila	2
20116002	RISPI	P6 Rispi n0 L22 ISO M07	P6 Rispi n0 L22 ISO M07	Ila	2
20116003	RISPI	P6 Rispi n1 L19 ISO M07	P6 Rispi n1 L19 ISO M07	Ila	2
20116004	RISPI	P6 Rispi n1 L22 ISO M07	P6 Rispi n1 L22 ISO M07	Ila	2
20116005	RISPI	P6 Rispi n2 L19 ISO M07	P6 Rispi n2 L19 ISO M07	Ila	2
20116006	RISPI	P6 Rispi n2 L22 ISO M07	P6 Rispi n2 L22 ISO M07	Ila	2
20116007	RISPI	P6 Rispi n3 L19 ISO M07	P6 Rispi n3 L19 ISO M07	Ila	2
20116008	RISPI	P6 Rispi n3 L22 ISO M07	P6 Rispi n3 L22 ISO M07	Ila	2
20116009	RISPI	P6 Rispi n4 L19 ISO M07	P6 Rispi n4 L19 ISO M07	Ila	2
20116010	RISPI	P6 Rispi n4 L22 ISO M07	P6 Rispi n4 L22 ISO M07	Ila	2
20116011	RISPI	P6 Rispi n5 L19 ISO M07	P6 Rispi n5 L19 ISO M07	Ila	2
20116012	RISPI	P6 Rispi n5 L22 ISO M07	P6 Rispi n5 L22 ISO M07	Ila	2
20116013	RISPI	P6 Rispi n6 L19 ISO M07	P6 Rispi n6 L19 ISO M07	Ila	2
20116014	RISPI	P6 Rispi n6 L22 ISO M07	P6 Rispi n6 L22 ISO M07	Ila	2
20116015	RISPI	P6 Rispi 1/6 L19 ISO M07	P6 Rispi 1/6 L19 ISO M07	Ila	2
20116016	RISPI	P6 Rispi 1/6 L22 ISO M07	P6 Rispi 1/6 L22 ISO M07	Ila	2
20117001	RISPISONIC	P6 Rispisonic n0 L19 ISO M10	P6 Rispisonic n0 L19 ISO M10	Ila	3
20117002	RISPISONIC	P6 Rispisonic n0 L22 ISO M10	P6 Rispisonic n0 L22 ISO M10	Ila	3
20117003	RISPISONIC	P6 Rispisonic n1 L19 ISO M10	P6 Rispisonic n1 L19 ISO M10	Ila	3
20117004	RISPISONIC	P6 Rispisonic n1 L22 ISO M10	P6 Rispisonic n1 L22 ISO M10	Ila	3
20117005	RISPISONIC	P6 Rispisonic n2 L19 ISO M10	P6 Rispisonic n2 L19 ISO M10	Ila	3
20117006	RISPISONIC	P6 Rispisonic n2 L22 ISO M10	P6 Rispisonic n2 L22 ISO M10	Ila	3
20117007	RISPISONIC	P6 Rispisonic n3 L19 ISO M10	P6 Rispisonic n3 L19 ISO M10	Ila	3
20117008	RISPISONIC	P6 Rispisonic n3 L22 ISO M10	P6 Rispisonic n3 L22 ISO M10	Ila	3
20117009	RISPISONIC	P6 Rispisonic n4 L19 ISO M10	P6 Rispisonic n4 L19 ISO M10	Ila	3
20117010	RISPISONIC	P6 Rispisonic n4 L22 ISO M10	P6 Rispisonic n4 L22 ISO M10	Ila	3
20117011	RISPISONIC	P6 Rispisonic n5 L19 ISO M10	P6 Rispisonic n5 L19 ISO M10	Ila	3
20117012	RISPISONIC	P6 Rispisonic n5 L22 ISO M10	P6 Rispisonic n5 L22 ISO M10	Ila	3
20117013	RISPISONIC	P6 Rispisonic n6 L19 ISO M10	P6 Rispisonic n6 L19 ISO M10	Ila	3
20117014	RISPISONIC	P6 Rispisonic n6 L22 ISO M10	P6 Rispisonic n6 L22 ISO M10	Ila	3
20117015	RISPISONIC	P6 Rispisonic 1/6 L19 ISO M10	P6 Rispisonic 1/6 L19 ISO M10	Ila	3
20117016	RISPISONIC	P6 Rispisonic 1/6 L22 ISO M10	P6 Rispisonic 1/6 L22 ISO M10	Ila	3
20217001	RISPISONIC	P12 Rispisonic Asst 1/6 L:19 & 22mm	P12 Rispisonic Asst 1/6 L:19 & 22mm	Ila	3
20118001	SHAPER	P6 Shaper n10 L21 ISO M10	P6 Shaper n10 L21 ISO M10	Ila	3
20118002	SHAPER	P6 Shaper n10 L25 ISO M10	P6 Shaper n10 L25 ISO M10	Ila	3
20118003	SHAPER	P6 Shaper n15 L21 ISO M10	P6 Shaper n15 L21 ISO M10	Ila	3
20118004	SHAPER	P6 Shaper n15 L25 ISO M10	P6 Shaper n15 L25 ISO M10	Ila	3
20118005	SHAPER	P6 Shaper n20 L21 ISO M10	P6 Shaper n20 L21 ISO M10	Ila	3
20118006	SHAPER	P6 Shaper n20 L25 ISO M10	P6 Shaper n20 L25 ISO M10	Ila	3
20118007	SHAPER	P6 Shaper n25 L21 ISO M10	P6 Shaper n25 L21 ISO M10	Ila	3
20118008	SHAPER	P6 Shaper n25 L25 ISO M10	P6 Shaper n25 L25 ISO M10	Ila	3
20118009	SHAPER	P6 Shaper n30 L21 ISO M10	P6 Shaper n30 L21 ISO M10	Ila	3
20118010	SHAPER	P6 Shaper n30 L25 ISO M10	P6 Shaper n30 L25 ISO M10	Ila	3
20118011	SHAPER	P6 Shaper n35 L21 ISO M10	P6 Shaper n35 L21 ISO M10	Ila	3
20118012	SHAPER	P6 Shaper n35 L25 ISO M10	P6 Shaper n35 L25 ISO M10	Ila	3
20118013	SHAPER	P6 Shaper n40 L21 ISO M10	P6 Shaper n40 L21 ISO M10	Ila	3

Micro-Mega SA
12 rue du Tunnel
25000 BESANCON
France

GMED (0459) reconnaît que son certificat CE est valide pour
les dispositifs médicaux décrits le 12 mai 2021

GMED (0459) recognizes that its EC certificate is valid for the
medical devices listed on May 12, 2021

 **COLTENE**
MicroMega

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

Micro-Mega SA certifie que les produits suivants sont conformes à l'annexe I et VII de la directive 93/42 CEE relative aux dispositifs médicaux, en tenant compte de toutes les normes harmonisées européennes applicables et aux transpositions en droit national de chaque état et que son système d'assurance qualité, selon l'annexe II excluant le point 4 de la directive 93/42 CEE, est approuvé (Attestation CE n°8881 délivrée par l'organisme notifié GMED).

Micro-Mega SA certifies that the products listed below conform to annex I and VII of the Directive 93/42/EEC for medical devices, taking into account all applicable European harmonised standards and national laws for each state and that its full quality assurance system, according annex II excluding point 4 of the Directive 93/42/EEC, is approved (CE certificate n°8881 delivered by notified body GMED).

20118014	SHAPER	P6 Shaper n40 L25 ISO M10	P6 Shaper n40 L25 ISO M10	IIa	3
20118015	SHAPER	P6 Shaper 15/40 L21 ISO M10	P6 Shaper 15/40 L21 ISO M10	IIa	3
20118016	SHAPER	P6 Shaper 15/40 L25 ISO M10	P6 Shaper 15/40 L25 ISO M10	IIa	3
20218003	SHAPER	P12 Shaper Asst 15/40 L:21 & 25mm	P12 Shaper Asst 15/40 L:21 & 25mm	IIa	3
20122001	SPIRAL FILLERS	P4 Bourre-Pate n25 L21 ISO M07	P4 Spirall Filler n25 L21 ISO M07	IIa	10
20122002	SPIRAL FILLERS	P4 Bourre-Pate n25 L25 ISO M07	P4 Spirall Filler n25 L25 ISO M07	IIa	10
20122003	SPIRAL FILLERS	P4 Bourre-Pate n25 L29 ISO M07	P4 Spirall Filler n25 L29 ISO M07	IIa	10
20122004	SPIRAL FILLERS	P4 Bourre-Pate n30 L21 ISO M07	P4 Spirall Filler n30 L21 ISO M07	IIa	10
20122005	SPIRAL FILLERS	P4 Bourre-Pate n30 L25 ISO M07	P4 Spirall Filler n30 L25 ISO M07	IIa	10
20122006	SPIRAL FILLERS	P4 Bourre-Pate n30 L29 ISO M07	P4 Spirall Filler n30 L29 ISO M07	IIa	10
20122007	SPIRAL FILLERS	P4 Bourre-Pate n35 L21 ISO M07	P4 Spirall Filler n35 L21 ISO M07	IIa	10
20122008	SPIRAL FILLERS	P4 Bourre-Pate n35 L25 ISO M07	P4 Spirall Filler n35 L25 ISO M07	IIa	10
20122009	SPIRAL FILLERS	P4 Bourre-Pate n35 L29 ISO M07	P4 Spirall Filler n35 L29 ISO M07	IIa	10
20122010	SPIRAL FILLERS	P4 Bourre-Pate n40 L21 ISO M07	P4 Spirall Filler n40 L21 ISO M07	IIa	10
20122011	SPIRAL FILLERS	P4 Bourre-Pate n40 L25 ISO M07	P4 Spirall Filler n40 L25 ISO M07	IIa	10
20122013	SPIRAL FILLERS	P4 Bourre-Pate n45 L21 ISO M07	P4 Spirall Filler n45 L21 ISO M07	IIa	10
20122014	SPIRAL FILLERS	P4 Bourre-Pate n45 L25 ISO M07	P4 Spirall Filler n45 L25 ISO M07	IIa	10
20122016	SPIRAL FILLERS	P4 Bourre-Pate n50 L21 ISO M07	P4 Spirall Filler n50 L21 ISO M07	IIa	10
20122017	SPIRAL FILLERS	P4 Bourre-Pate n50 L25 ISO M07	P4 Spirall Filler n50 L25 ISO M07	IIa	10
20122028	SPIRAL FILLERS	P4 Bourre-Pate 25/40 L21 ISO M07	P4 Spirall Filler 25/40 L21 ISO M07	IIa	10
20122029	SPIRAL FILLERS	P4 Bourre-Pate 25/40 L25 ISO M07	P4 Spirall Filler 25/40 L25 ISO M07	IIa	10
20146000	HERO SHAPER	P4 Crown Down Rotary File n25 L15 12% ORBIS	P4 Crown Down Rotary File n25 L15 12% ORBIS	IIa	6
20154001PC	GENTAPER	P6 MULTITAPER SX n19 L19 PROCLINIC EXPERT	P6 MULTITAPER SX n19 L19 PROCLINIC EXPERT	IIa	6
20154002PC	GENTAPER	P6 MULTITAPER S1 n17 L21 PROCLINIC EXPERT	P6 MULTITAPER S1 n17 L21 PROCLINIC EXPERT	IIa	6
20154003PC	GENTAPER	P6 MULTITAPER S2 n20 L21 PROCLINIC EXPERT	P6 MULTITAPER S2 n20 L21 PROCLINIC EXPERT	IIa	6
20154004PC	GENTAPER	P6 MULTITAPER F1 n20 L21 PROCLINIC EXPERT	P6 MULTITAPER F1 n20 L21 PROCLINIC EXPERT	IIa	6
20154005PC	GENTAPER	P6 MULTITAPER F2 n25 L21 PROCLINIC EXPERT	P6 MULTITAPER F2 n25 L21 PROCLINIC EXPERT	IIa	6
20154006PC	GENTAPER	P6 MULTITAPER F3 n30 L21 PROCLINIC EXPERT	P6 MULTITAPER F3 n30 L21 PROCLINIC EXPERT	IIa	6
20154012PC	GENTAPER	P6 MULTITAPER S1 n17 L25 PROCLINIC EXPERT	P6 MULTITAPER S1 n17 L25 PROCLINIC EXPERT	IIa	6
20154013PC	GENTAPER	P6 MULTITAPER S2 n20 L25 PROCLINIC EXPERT	P6 MULTITAPER S2 n20 L25 PROCLINIC EXPERT	IIa	6
20154014PC	GENTAPER	P6 MULTITAPER F1 n20 L25 PROCLINIC EXPERT	P6 MULTITAPER F1 n20 L25 PROCLINIC EXPERT	IIa	6
20154015PC	GENTAPER	P6 MULTITAPER F2 n25 L25 PROCLINIC EXPERT	P6 MULTITAPER F2 n25 L25 PROCLINIC EXPERT	IIa	6
20154016PC	GENTAPER	P6 MULTITAPER F3 n30 L25 PROCLINIC EXPERT	P6 MULTITAPER F3 n30 L25 PROCLINIC EXPERT	IIa	6
20154022PC	GENTAPER	P6 MULTITAPER S1 n17 L31 PROCLINIC EXPERT	P6 MULTITAPER S1 n17 L31 PROCLINIC EXPERT	IIa	6
20154023PC	GENTAPER	P6 MULTITAPER S2 n20 L31 PROCLINIC EXPERT	P6 MULTITAPER S2 n20 L31 PROCLINIC EXPERT	IIa	6
20154024PC	GENTAPER	P6 MULTITAPER F1 n20 L31 PROCLINIC EXPERT	P6 MULTITAPER F1 n20 L31 PROCLINIC EXPERT	IIa	6
20154025PC	GENTAPER	P6 MULTITAPER F2 n25 L31 PROCLINIC EXPERT	P6 MULTITAPER F2 n25 L31 PROCLINIC EXPERT	IIa	6
20154026PC	GENTAPER	P6 MULTITAPER F3 n30 L31 PROCLINIC EXPERT	P6 MULTITAPER F3 n30 L31 PROCLINIC EXPERT	IIa	6
20154030PC	GENTAPER	P6 MULTITAPER STARTER KIT L21 PROCLINIC EXPERT	P6 MULTITAPER STARTER KIT L21 PROCLINIC EXPERT	IIa	6
20154031PC	GENTAPER	P6 MULTITAPER STARTER KIT L25 PROCLINIC EXPERT	P6 MULTITAPER STARTER KIT L25 PROCLINIC EXPERT	IIa	6
20154032PC	GENTAPER	P6 MULTITAPER STARTER KIT L31 PROCLINIC EXPERT	P6 MULTITAPER STARTER KIT L31 PROCLINIC EXPERT	IIa	6
63980	GENTAPER	MULTITAPER STARTER KIT 21mm 5u. (63980)	MULTITAPER STARTER KIT 21mm 5u. (63980)	IIa	6
63981	GENTAPER	MULTITAPER STARTER KIT 25mm 5u. (63981)	MULTITAPER STARTER KIT 25mm 5u. (63981)	IIa	6
63982	GENTAPER	MULTITAPER STARTER KIT 31mm 5u. (63982)	MULTITAPER STARTER KIT 31mm 5u. (63982)	IIa	6
63983	GENTAPER	LIMAS MULTITAPER SX 19mm 5u. (63983)	LIMAS MULTITAPER SX 19mm 5u. (63983)	IIa	6
63984	GENTAPER	LIMAS MULTITAPER S1 21mm 5u. (63984)	LIMAS MULTITAPER S1 21mm 5u. (63984)	IIa	6
63985	GENTAPER	LIMAS MULTITAPER S1 25mm 5u. (63985)	LIMAS MULTITAPER S1 25mm 5u. (63985)	IIa	6
63986	GENTAPER	LIMAS MULTITAPER S1 31mm 5u. (63986)	LIMAS MULTITAPER S1 31mm 5u. (63986)	IIa	6
63987	GENTAPER	LIMAS MULTITAPER S2 21mm 5u. (63987)	LIMAS MULTITAPER S2 21mm 5u. (63987)	IIa	6
63988	GENTAPER	LIMAS MULTITAPER S2 25mm 5u. (63988)	LIMAS MULTITAPER S2 25mm 5u. (63988)	IIa	6
63989	GENTAPER	LIMAS MULTITAPER S2 31mm 5u. (63989)	LIMAS MULTITAPER S2 31mm 5u. (63989)	IIa	6
63990	GENTAPER	LIMAS MULTITAPER F1 21mm 5u. (63990)	LIMAS MULTITAPER F1 21mm 5u. (63990)	IIa	6
63991	GENTAPER	LIMAS MULTITAPER F1 25mm 5u. (63991)	LIMAS MULTITAPER F1 25mm 5u. (63991)	IIa	6
63992	GENTAPER	LIMAS MULTITAPER F1 31mm 5u. (63992)	LIMAS MULTITAPER F1 31mm 5u. (63992)	IIa	6
63993	GENTAPER	LIMAS MULTITAPER F2 21mm 5u. (63993)	LIMAS MULTITAPER F2 21mm 5u. (63993)	IIa	6
63994	GENTAPER	LIMAS MULTITAPER F2 25mm 5u. (63994)	LIMAS MULTITAPER F2 25mm 5u. (63994)	IIa	6
63995	GENTAPER	LIMAS MULTITAPER F2 31mm 5u. (63995)	LIMAS MULTITAPER F2 31mm 5u. (63995)	IIa	6

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA
Stéphane CLAUDE
Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

Micro-Mega SA certifie que les produits suivants sont conformes à l'annexe I et VII de la directive 93/42 CEE relative aux dispositifs médicaux, en tenant compte de toutes les normes harmonisées européennes applicables et aux transpositions en droit national de chaque état et que son système d'assurance qualité, selon l'annexe II excluant le point 4 de la directive 93/42 CEE, est approuvé (Attestation CE n°8881 délivrée par l'organisme notifié GMED).

Micro-Mega SA certifies that the products listed below conform to annex I and VII of the Directive 93/42/EEC for medical devices, taking into account all applicable European harmonised standards and national laws for each state and that it full quality assurance system, according annex II excluding point 4 of the Directive 93/42/EEC, is approved (CE certificate n°8881 delivered by notified body GMED).

63996	GENTAPER	LIMAS MULTITAPER F3 21mm 5u. (63996)	LIMAS MULTITAPER F3 21mm 5u. (63996)	Ila	6
63997	GENTAPER	LIMAS MULTITAPER F3 25mm 5u. (63997)	LIMAS MULTITAPER F3 25mm 5u. (63997)	Ila	6
63998	GENTAPER	LIMAS MULTITAPER F3 31mm 5u. (63998)	LIMAS MULTITAPER F3 31mm 5u. (63998)	Ila	6
20137612	ENDOPRED	P6 ENDOPRED P1 n20 L25 4% Classics	P6 ENDOPRED P1 n20 L25 4% Classics	Ila	6
20137613	ENDOPRED	P6 ENDOPRED P2 n20 L25 6% Classics	P6 ENDOPRED P2 n20 L25 6% Classics	Ila	6
20137614	ENDOPRED	P6 ENDOPRED P3 n25 L25 6% Classics	P6 ENDOPRED P3 n25 L25 6% Classics	Ila	6
20137618	ENDOPRED	P5 ENDOPRED Asst P1 P2 P3	P5 ENDOPRED Asst P1 P2 P3	Ila	6
20955102	GENGIRO	B5 Alter Endo A25 L21 Classics PRED sterile	B5 Alter Endo A25 L21 Classics PRED sterile	Ila	2
20955105	GENGIRO	B5 Alter Endo A40 L21 Classics PRED sterile	B5 Alter Endo A40 L21 Classics PRED sterile	Ila	2
20955107	GENGIRO	B5 Alter Endo A50 L21 Classics PRED sterile	B5 Alter Endo A50 L21 Classics PRED sterile	Ila	2
20955112	GENGIRO	B5 Alter Endo A25 L25 Classics PRED sterile	B5 Alter Endo A25 L25 Classics PRED sterile	Ila	2
20955115	GENGIRO	B5 Alter Endo A40 L25 Classics PRED sterile	B5 Alter Endo A40 L25 Classics PRED sterile	Ila	2
20955117	GENGIRO	B5 Alter Endo A50 L25 Classics PRED sterile	B5 Alter Endo A50 L25 Classics PRED sterile	Ila	2
20955122	GENGIRO	B5 Alter Endo A25 L31 Classics PRED sterile	B5 Alter Endo A25 L31 Classics PRED sterile	Ila	2
20955125	GENGIRO	B5 Alter Endo A40 L31 Classics PRED sterile	B5 Alter Endo A40 L31 Classics PRED sterile	Ila	2
20955127	GENGIRO	B5 Alter Endo A50 L31 Classics PRED sterile	B5 Alter Endo A50 L31 Classics PRED sterile	Ila	2
20137630	SEQUENCE ISI	P4 Isi-ENDO Asst Classics	P4 Isi-ENDO Asst Classics	Ila	6
20137631	SEQUENCE ISI	P6 Isi-OPEN n20 L25 4% Classics	P6 Isi-OPEN n20 L25 4% Classics	Ila	6
20137632	SEQUENCE ISI	P6 Isi-SAFE n25 L25 5% Classics	P6 Isi-SAFE n25 L25 5% Classics	Ila	6
20137633	SEQUENCE ISI	P6 Isi-SHAPE 25 L25 7% Classics	P6 Isi-SHAPE 25 L25 7% Classics	Ila	6
20149436	One Curve	P3 One Curve n25 4% L21 Classics	P3 One Curve n25 4% L21 Classics	Ila	6
20149437	One Curve	P3 One Curve n35 4% L21 Classics	P3 One Curve n35 4% L21 Classics	Ila	6
20149438	One Curve	P3 One Curve n45 4% L21 Classics	P3 One Curve n45 4% L21 Classics	Ila	6
20149446	One Curve	P3 One Curve n25 4% L25 Classics	P3 One Curve n25 4% L25 Classics	Ila	6
20149447	One Curve	P3 One Curve n35 4% L25 Classics	P3 One Curve n35 4% L25 Classics	Ila	6
20149448	One Curve	P3 One Curve n45 4% L25 Classics	P3 One Curve n45 4% L25 Classics	Ila	6
20149456	One Curve	P3 One Curve n25 4% L31 Classics	P3 One Curve n25 4% L31 Classics	Ila	6
20149457	One Curve	P3 One Curve n35 4% L31 Classics	P3 One Curve n35 4% L31 Classics	Ila	6
20149458	One Curve	P3 One Curve n45 4% L31 Classics	P3 One Curve n45 4% L31 Classics	Ila	6
20149431	One Curve	P6 One Curve n25 4% L21 Classics	P6 One Curve n25 4% L21 Classics	Ila	6
20149432	One Curve	P6 One Curve n35 4% L21 Classics	P6 One Curve n35 4% L21 Classics	Ila	6
20149433	One Curve	P6 One Curve n45 4% L21 Classics	P6 One Curve n45 4% L21 Classics	Ila	6
20149441	One Curve	P6 One Curve n25 4% L25 Classics	P6 One Curve n25 4% L25 Classics	Ila	6
20149442	One Curve	P6 One Curve n35 4% L25 Classics	P6 One Curve n35 4% L25 Classics	Ila	6
20149443	One Curve	P6 One Curve n45 4% L25 Classics	P6 One Curve n45 4% L25 Classics	Ila	6
20149451	One Curve	P6 One Curve n25 4% L31 Classics	P6 One Curve n25 4% L31 Classics	Ila	6
20149452	One Curve	P6 One Curve n35 4% L31 Classics	P6 One Curve n35 4% L31 Classics	Ila	6
20149453	One Curve	P6 One Curve n45 4% L31 Classics	P6 One Curve n45 4% L31 Classics	Ila	6
20149435	One Curve	P4 One Curve L21 Asst STARTER PACK	P4 One Curve L21 Asst STARTER PACK	Ila	6
20149445	One Curve	P4 One Curve L25 Asst STARTER PACK	P4 One Curve L25 Asst STARTER PACK	Ila	6
20149455	One Curve	P4 One Curve L31 Asst STARTER PACK	P4 One Curve L31 Asst STARTER PACK	Ila	6
20149461	One Curve	P4 One Curve n25 4% L21 PROCEDURE PACK	P4 One Curve n25 4% L21 PROCEDURE PACK	Ila	6
20149462	One Curve	P4 One Curve n35 4% L21 PROCEDURE PACK	P4 One Curve n35 4% L21 PROCEDURE PACK	Ila	6
20149463	One Curve	P4 One Curve n45 4% L21 PROCEDURE PACK	P4 One Curve n45 4% L21 PROCEDURE PACK	Ila	6
20149471	One Curve	P4 One Curve n25 4% L25 PROCEDURE PACK	P4 One Curve n25 4% L25 PROCEDURE PACK	Ila	6
20149472	One Curve	P4 One Curve n35 4% L25 PROCEDURE PACK	P4 One Curve n35 4% L25 PROCEDURE PACK	Ila	6
20149473	One Curve	P4 One Curve n45 4% L25 PROCEDURE PACK	P4 One Curve n45 4% L25 PROCEDURE PACK	Ila	6
20149481	One Curve	P4 One Curve n25 4% L31 PROCEDURE PACK	P4 One Curve n25 4% L31 PROCEDURE PACK	Ila	6
20149482	One Curve	P4 One Curve n35 4% L31 PROCEDURE PACK	P4 One Curve n35 4% L31 PROCEDURE PACK	Ila	6
20149483	One Curve	P4 One Curve n45 4% L31 PROCEDURE PACK	P4 One Curve n45 4% L31 PROCEDURE PACK	Ila	6
20949431	One Curve	B5 One Curve n25 4% L21 Classics	B5 One Curve n25 4% L21 Classics	Ila	6
20949432	One Curve	B5 One Curve n35 4% L21 Classics	B5 One Curve n35 4% L21 Classics	Ila	6
20949433	One Curve	B5 One Curve n45 4% L21 Classics	B5 One Curve n45 4% L21 Classics	Ila	6
20949441	One Curve	B5 One Curve n25 4% L25 Classics	B5 One Curve n25 4% L25 Classics	Ila	6
20949442	One Curve	B5 One Curve n35 4% L25 Classics	B5 One Curve n35 4% L25 Classics	Ila	6
20949443	One Curve	B5 One Curve n45 4% L25 Classics	B5 One Curve n45 4% L25 Classics	Ila	6
20949451	One Curve	B5 One Curve n25 4% L31 Classics	B5 One Curve n25 4% L31 Classics	Ila	6

Micro-Mega SA
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France

GMED (0459) reconnait que son certificat CE est valide pour les dispositifs médicaux décrits le 12 mai 2021

GMED (0459) recognises that its CE certificate is valid for the medical devices listed on May 12, 2021

COLTENE
MicroMega

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

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20949452	One Curve	B5 One Curve n35 4% L31 Classics	B5 One Curve n35 4% L31 Classics	Ila	6
20949453	One Curve	B5 One Curve n45 4% L31 Classics	B5 One Curve n45 4% L31 Classics	Ila	6
20949461	One Curve	B4 One Curve n25 4% L21 PROCEDURE PACK Sterile	B4 One Curve n25 4% L21 PROCEDURE PACK Sterile	Ila	6
20949462	One Curve	B4 One Curve n35 4% L21 PROCEDURE PACK Sterile	B4 One Curve n35 4% L21 PROCEDURE PACK Sterile	Ila	6
20949463	One Curve	B4 One Curve n45 4% L21 PROCEDURE PACK Sterile	B4 One Curve n45 4% L21 PROCEDURE PACK Sterile	Ila	6
20949471	One Curve	B4 One Curve n25 4% L25 PROCEDURE PACK Sterile	B4 One Curve n25 4% L25 PROCEDURE PACK Sterile	Ila	6
20949472	One Curve	B4 One Curve n35 4% L25 PROCEDURE PACK Sterile	B4 One Curve n35 4% L25 PROCEDURE PACK Sterile	Ila	6
20949473	One Curve	B4 One Curve n45 4% L25 PROCEDURE PACK Sterile	B4 One Curve n45 4% L25 PROCEDURE PACK Sterile	Ila	6
20949481	One Curve	B4 One Curve n25 4% L31 PROCEDURE PACK Sterile	B4 One Curve n25 4% L31 PROCEDURE PACK Sterile	Ila	6
20949482	One Curve	B4 One Curve n35 4% L31 PROCEDURE PACK Sterile	B4 One Curve n35 4% L31 PROCEDURE PACK Sterile	Ila	6
20949483	One Curve	B4 One Curve n45 4% L31 PROCEDURE PACK Sterile	B4 One Curve n45 4% L31 PROCEDURE PACK Sterile	Ila	6
20949435	One Curve	B4 One Curve L21 Asst STARTER PACK Sterile	B4 One Curve L21 Asst STARTER PACK Sterile	Ila	6
20949445	One Curve	B4 One Curve L25 Asst STARTER PACK Sterile	B4 One Curve L25 Asst STARTER PACK Sterile	Ila	6
20949455	One Curve	B4 One Curve L31 Asst STARTER PACK Sterile	B4 One Curve L31 Asst STARTER PACK Sterile	Ila	6
60023811	REMOVER	P3 Remover L19 n30 7% Classics	P3 Remover L19 n30 7% Classics	Ila	6
60023812	REMOVER	P3 Remover L23 n30 7% Classics	P3 Remover L23 n30 7% Classics	Ila	6
60023813	REMOVER	P6 Remover L19 n30 7% Classics	P6 Remover L19 n30 7% Classics	Ila	6
60023814	REMOVER	P6 Remover L23 n30 7% Classics	P6 Remover L23 n30 7% Classics	Ila	6
60023653	REMOVER	P3 HyFlex Remover L19 n30 7% Classics	P3 HyFlex Remover L19 n30 7% Classics	Ila	6
60023652	REMOVER	P3 HyFlex Remover L23 n30 7% Classics	P3 HyFlex Remover L23 n30 7% Classics	Ila	6
60023651	REMOVER	P6 HyFlex Remover L19 n30 7% Classics	P6 HyFlex Remover L19 n30 7% Classics	Ila	6
60023650	REMOVER	P6 HyFlex Remover L23 n30 7% Classics	P6 HyFlex Remover L23 n30 7% Classics	Ila	6
20152302	REMOVER	P3 MicroMega Remover L19 n30 7% Classics	P3 MicroMega Remover L19 n30 7% Classics	Ila	6
20152312	REMOVER	P3 MicroMega Remover L23 n30 7% Classics	P3 MicroMega Remover L23 n30 7% Classics	Ila	6
20152301	REMOVER	P6 MicroMega Remover L19 n30 7% Classics	P6 MicroMega Remover L19 n30 7% Classics	Ila	6
20152311	REMOVER	P6 MicroMega Remover L23 n30 7% Classics	P6 MicroMega Remover L23 n30 7% Classics	Ila	6
20152303	REMOVER	P4 Remover L19 n30 7% STARTER PACK	P4 Remover L19 n30 7% STARTER PACK	Ila	6
20152313	REMOVER	P4 Remover L23 n30 7% STARTER PACK	P4 Remover L23 n30 7% STARTER PACK	Ila	6
60023815	REMOVER	B5 Remover L19 n30 7% Classics	B5 Remover L19 n30 7% Classics	Ila	6
60023816	REMOVER	B5 Remover L23 n30 7% Classics	B5 Remover L23 n30 7% Classics	Ila	6
60023649	REMOVER	B5 HyFlex Remover L19 n30 7% Classics	B5 HyFlex Remover L19 n30 7% Classics	Ila	6
60023648	REMOVER	B5 HyFlex Remover L23 n30 7% Classics	B5 HyFlex Remover L23 n30 7% Classics	Ila	6
20952301	REMOVER	B5 MicroMega Remover L19 n30 7% Classics	B5 MicroMega Remover L19 n30 7% Classics	Ila	6
20952311	REMOVER	B5 MicroMega Remover L23 n30 7% Classics	B5 MicroMega Remover L23 n30 7% Classics	Ila	6
20952303	REMOVER	B4 Remover L19 n30 7% STARTER PACK Sterile	B4 Remover L19 n30 7% STARTER PACK Sterile	Ila	6
20952313	REMOVER	B4 Remover L23 n30 7% STARTER PACK Sterile	B4 Remover L23 n30 7% STARTER PACK Sterile	Ila	6
21953001	2Shape	E5 2Shape TS1 n25 4% L21 No Stérile	E5 2Shape TS1 n25 4% L21 No Stérile	Ila	6
21953002	2Shape	E5 2Shape TS2 n25 6% L21 No Stérile	E5 2Shape TS2 n25 6% L21 No Stérile	Ila	6
21953003	2Shape	E5 2Shape F35 n35 6% L21 No Stérile	E5 2Shape F35 n35 6% L21 No Stérile	Ila	6
21953004	2Shape	E5 2Shape F40 n40 4% L21 No Stérile	E5 2Shape F40 n40 4% L21 No Stérile	Ila	6
21953011	2Shape	E5 2Shape TS1 n25 4% L25 No Stérile	E5 2Shape TS1 n25 4% L25 No Stérile	Ila	6
21953012	2Shape	E5 2Shape TS2 n25 6% L25 No Stérile	E5 2Shape TS2 n25 6% L25 No Stérile	Ila	6
21953013	2Shape	E5 2Shape F35 n35 6% L25 No Stérile	E5 2Shape F35 n35 6% L25 No Stérile	Ila	6
21953014	2Shape	E5 2Shape F40 n40 4% L25 No Stérile	E5 2Shape F40 n40 4% L25 No Stérile	Ila	6
21953021	2Shape	E5 2Shape TS1 n25 4% L31 No Stérile	E5 2Shape TS1 n25 4% L31 No Stérile	Ila	6
21953022	2Shape	E5 2Shape TS2 n25 6% L31 No Stérile	E5 2Shape TS2 n25 6% L31 No Stérile	Ila	6
21953023	2Shape	E5 2Shape F35 n35 6% L31 No Stérile	E5 2Shape F35 n35 6% L31 No Stérile	Ila	6
21953024	2Shape	E5 2Shape F40 n40 4% L31 No Stérile	E5 2Shape F40 n40 4% L31 No Stérile	Ila	6
21953031	2Shape	E4 2Shape 2xTS1+2xTS2 L21 No Stérile	E4 2Shape 2xTS1+2xTS2 L21 No Stérile	Ila	6
21953032	2Shape	E4 2Shape 2xTS1+2xTS2 L25 No Stérile	E4 2Shape 2xTS1+2xTS2 L25 No Stérile	Ila	6
21953033	2Shape	E4 2Shape 2xTS1+2xTS2 L31 No Stérile	E4 2Shape 2xTS1+2xTS2 L31 No Stérile	Ila	6
21953111	2Shape	E5 2Shape Procedure Pack L21 No Stérile	E5 2Shape Procedure Pack L21 No Stérile	Ila	6
21953112	2Shape	E5 2Shape Procedure Pack L25 No Stérile	E5 2Shape Procedure Pack L25 No Stérile	Ila	6
21953113	2Shape	E5 2Shape Procedure Pack L31 No Stérile	E5 2Shape Procedure Pack L31 No Stérile	Ila	6
20153201	2Shape	P6 2Shape TS1 Mini n25 4% L21 Classics	P6 2Shape TS1 Mini n25 4% L21 Classics	Ila	6
20153202	2Shape	P6 2Shape TS2 Mini n25 6% L21 Classics	P6 2Shape TS2 Mini n25 6% L21 Classics	Ila	6
20153203	2Shape	P6 2Shape F35 Mini n35 6% L21 Classics	P6 2Shape F35 Mini n35 6% L21 Classics	Ila	6

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA
Stéphane CLAUDE
Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

Micro-Mega SA
12 rue du Tunnel
25000 BESANCON
France

GMED (0459) reconnaît que son certificat CE est valide pour
les dispositifs médicaux décrits le 12 mai 2021

GMED (0459) recognizes that its CE certificate is valid for the
medical devices listed on May 12, 2021

 **COLTENE**
MicroMega

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

Micro-Mega SA certifie que les produits suivants sont conformes à l'annexe I et VII de la directive 93/42 CEE relative aux dispositifs médicaux, en tenant compte de toutes les normes harmonisées européennes applicables et aux transpositions en droit national de chaque état et que son système d'assurance qualité, selon l'annexe II excluant le point 4 de la directive 93/42 CEE, est approuvé (Attestation CE n°8881 délivrée par l'organisme notifié GMED).

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20153204	2Shape	P6 2Shape F40 Mini n40 4% L21 Classics	P6 2Shape F40 Mini n40 4% L21 Classics	Ila	6
20153211	2Shape	P6 2Shape TS1 Mini n25 4% L25 Classics	P6 2Shape TS1 Mini n25 4% L25 Classics	Ila	6
20153212	2Shape	P6 2Shape TS2 Mini n25 6% L25 Classics	P6 2Shape TS2 Mini n25 6% L25 Classics	Ila	6
20153213	2Shape	P6 2Shape F35 Mini n35 6% L25 Classics	P6 2Shape F35 Mini n35 6% L25 Classics	Ila	6
20153214	2Shape	P6 2Shape F40 Mini n40 4% L25 Classics	P6 2Shape F40 Mini n40 4% L25 Classics	Ila	6
20153221	2Shape	P6 2Shape TS1 Mini n25 4% L31 Classics	P6 2Shape TS1 Mini n25 4% L31 Classics	Ila	6
20153222	2Shape	P6 2Shape TS2 Mini n25 6% L31 Classics	P6 2Shape TS2 Mini n25 6% L31 Classics	Ila	6
20153223	2Shape	P6 2Shape F35 Mini n35 6% L31 Classics	P6 2Shape F35 Mini n35 6% L31 Classics	Ila	6
20153224	2Shape	P6 2Shape F40 Mini n40 4% L31 Classics	P6 2Shape F40 Mini n40 4% L31 Classics	Ila	6
20153231	2Shape	P4 2Shape Mini TS1+2xTS2 (x2) L21 Classics	P4 2Shape Mini TS1+2xTS2 (x2) L21 Classics	Ila	6
20153232	2Shape	P4 2Shape Mini TS1+2xTS2 (x2) L25 Classics	P4 2Shape Mini TS1+2xTS2 (x2) L25 Classics	Ila	6
20153233	2Shape	P4 2Shape Mini TS1+2xTS2 (x2) L31 Classics	P4 2Shape Mini TS1+2xTS2 (x2) L31 Classics	Ila	6
20953201	2Shape	B5 2Shape TS1 Mini n25 4% L21 Classics sterile	B5 2Shape TS1 Mini n25 4% L21 Classics sterile	Ila	6
20953202	2Shape	B5 2Shape TS2 Mini n25 6% L21 Classics sterile	B5 2Shape TS2 Mini n25 6% L21 Classics sterile	Ila	6
20953203	2Shape	B5 2Shape F35 Mini n35 6% L21 Classics sterile	B5 2Shape F35 Mini n35 6% L21 Classics sterile	Ila	6
20953204	2Shape	B5 2Shape F40 Mini n40 4% L21 Classics sterile	B5 2Shape F40 Mini n40 4% L21 Classics sterile	Ila	6
20953211	2Shape	B5 2Shape TS1 Mini n25 4% L25 Classics sterile	B5 2Shape TS1 Mini n25 4% L25 Classics sterile	Ila	6
20953212	2Shape	B5 2Shape TS2 Mini n25 6% L25 Classics sterile	B5 2Shape TS2 Mini n25 6% L25 Classics sterile	Ila	6
20953213	2Shape	B5 2Shape F35 Mini n35 6% L25 Classics sterile	B5 2Shape F35 Mini n35 6% L25 Classics sterile	Ila	6
20953214	2Shape	B5 2Shape F40 Mini n40 4% L25 Classics sterile	B5 2Shape F40 Mini n40 4% L25 Classics sterile	Ila	6
20953221	2Shape	B5 2Shape TS1 Mini n25 4% L31 Classics sterile	B5 2Shape TS1 Mini n25 4% L31 Classics sterile	Ila	6
20953222	2Shape	B5 2Shape TS2 Mini n25 6% L31 Classics sterile	B5 2Shape TS2 Mini n25 6% L31 Classics sterile	Ila	6
20953223	2Shape	B5 2Shape F35 Mini n35 6% L31 Classics sterile	B5 2Shape F35 Mini n35 6% L31 Classics sterile	Ila	6
20953224	2Shape	B5 2Shape F40 Mini n40 4% L31 Classics sterile	B5 2Shape F40 Mini n40 4% L31 Classics sterile	Ila	6
20953231	2Shape	B4 2Shape Mini TS1+2xTS2 L21 (x2) Classics Sterile	B4 2Shape Mini TS1+2xTS2 L21 (x2) Classics Sterile	Ila	6
20953232	2Shape	B4 2Shape Mini TS1+2xTS2 L25 (x2) Classics Sterile	B4 2Shape Mini TS1+2xTS2 L25 (x2) Classics Sterile	Ila	6
20953233	2Shape	B4 2Shape Mini TS1+2xTS2 L31 (x2) Classics Sterile	B4 2Shape Mini TS1+2xTS2 L31 (x2) Classics Sterile	Ila	6
20953241	2Shape	B5 2Shape Mini Procedure Pack L21 Classics sterile	B5 2Shape Mini Procedure Pack L21 Classics sterile	Ila	6
20953242	2Shape	B5 2Shape Mini Procedure Pack L25 Classics sterile	B5 2Shape Mini Procedure Pack L25 Classics sterile	Ila	6
20953243	2Shape	B5 2Shape Mini Procedure Pack L31 Classics sterile	B5 2Shape Mini Procedure Pack L31 Classics sterile	Ila	6
21953201	2Shape	E5 2Shape TS1 Mini n25 4% L21 Classics No sterile	E5 2Shape TS1 Mini n25 4% L21 Classics No sterile	Ila	6
21953202	2Shape	E5 2Shape TS2 Mini n25 6% L21 Classics No sterile	E5 2Shape TS2 Mini n25 6% L21 Classics No sterile	Ila	6
21953203	2Shape	E5 2Shape F35 Mini n35 6% L21 Classics No sterile	E5 2Shape F35 Mini n35 6% L21 Classics No sterile	Ila	6
21953204	2Shape	E5 2Shape F40 Mini n40 4% L21 Classics No sterile	E5 2Shape F40 Mini n40 4% L21 Classics No sterile	Ila	6
21953211	2Shape	E5 2Shape TS1 Mini n25 4% L25 Classics No sterile	E5 2Shape TS1 Mini n25 4% L25 Classics No sterile	Ila	6
21953212	2Shape	E5 2Shape TS2 Mini n25 6% L25 Classics No sterile	E5 2Shape TS2 Mini n25 6% L25 Classics No sterile	Ila	6
21953213	2Shape	E5 2Shape F35 Mini n35 6% L25 Classics No sterile	E5 2Shape F35 Mini n35 6% L25 Classics No sterile	Ila	6
21953214	2Shape	E5 2Shape F40 Mini n40 4% L25 Classics No sterile	E5 2Shape F40 Mini n40 4% L25 Classics No sterile	Ila	6
21953221	2Shape	E5 2Shape TS1 Mini n25 4% L31 Classics No sterile	E5 2Shape TS1 Mini n25 4% L31 Classics No sterile	Ila	6
21953222	2Shape	E5 2Shape TS2 Mini n25 6% L31 Classics No sterile	E5 2Shape TS2 Mini n25 6% L31 Classics No sterile	Ila	6
21953223	2Shape	E5 2Shape F35 Mini n35 6% L31 Classics No sterile	E5 2Shape F35 Mini n35 6% L31 Classics No sterile	Ila	6
21953224	2Shape	E5 2Shape F40 Mini n40 4% L31 Classics No sterile	E5 2Shape F40 Mini n40 4% L31 Classics No sterile	Ila	6
21953231	2Shape	E4 2Shape Mini 2xTS1+2xTS2 L21 (x2) Classics no sterile	E4 2Shape Mini 2xTS1+2xTS2 L21 (x2) Classics no sterile	Ila	6
21953232	2Shape	E4 2Shape Mini 2xTS1+2xTS2 L25 (x2) Classics no sterile	E4 2Shape Mini 2xTS1+2xTS2 L25 (x2) Classics no sterile	Ila	6
21953233	2Shape	E4 2Shape Mini 2xTS1+2xTS2 L31 (x2) Classics no sterile	E4 2Shape Mini 2xTS1+2xTS2 L31 (x2) Classics no sterile	Ila	6
21953241	2Shape	E5 2Shape Mini Procedure Pack L21 Classics no sterile	E5 2Shape Mini Procedure Pack L21 Classics no sterile	Ila	6
21953242	2Shape	E5 2Shape Mini Procedure Pack L25 Classics no sterile	E5 2Shape Mini Procedure Pack L25 Classics no sterile	Ila	6
21953243	2Shape	E5 2Shape Mini Procedure Pack L31 Classics no sterile	E5 2Shape Mini Procedure Pack L31 Classics no sterile	Ila	6

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA
Stéphane CLAUDE
Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

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60031633	One Flare	B1 ONE FLARE n25 9% L17 Classics sterile	B1 ONE FLARE n25 9% L17 Classics sterile	Ila	6
60031634	One G	B1 One G n14 3% L21 Classics sterile	B1 One G n14 3% L21 Classics sterile	Ila	6
60031635	One G	B1 One G n14 3% L25 Classics sterile	B1 One G n14 3% L25 Classics sterile	Ila	6
60031636	One G	B1 One G n14 3% L29 Classics sterile	B1 One G n14 3% L29 Classics sterile	Ila	6
60031637	One Curve	B1 ONE CURVE n25 6% L21 Sterile	B1 ONE CURVE n25 6% L21 Sterile	Ila	6
60031638	One Curve	B1 ONE CURVE n25 6% L25 Sterile	B1 ONE CURVE n25 6% L25 Sterile	Ila	6
60031639	One Curve	B1 ONE CURVE n25 6% L31 Sterile	B1 ONE CURVE n25 6% L31 Sterile	Ila	6
60031640	One Curve	B1 One Curve n25 4% L21 Classics	B1 One Curve n25 4% L21 Classics	Ila	6
60031641	One Curve	B1 One Curve n35 4% L21 Classics	B1 One Curve n35 4% L21 Classics	Ila	6
60031642	One Curve	B1 One Curve n45 4% L21 Classics	B1 One Curve n45 4% L21 Classics	Ila	6
60031643	One Curve	B1 One Curve n25 4% L25 Classics	B1 One Curve n25 4% L25 Classics	Ila	6
60031644	One Curve	B1 One Curve n35 4% L25 Classics	B1 One Curve n35 4% L25 Classics	Ila	6
60031645	One Curve	B1 One Curve n45 4% L25 Classics	B1 One Curve n45 4% L25 Classics	Ila	6
60031646	One Curve	B1 One Curve n25 4% L31 Classics	B1 One Curve n25 4% L31 Classics	Ila	6
60031647	One Curve	B1 One Curve n35 4% L31 Classics	B1 One Curve n35 4% L31 Classics	Ila	6
60031648	One Curve	B1 One Curve n45 4% L31 Classics	B1 One Curve n45 4% L31 Classics	Ila	6
60031649	2Shape	B1 2Shape TS1 n25 4% L21 Classics sterile	B1 2Shape TS1 n25 4% L21 Classics sterile	Ila	6
60031650	2Shape	B1 2Shape TS2 n25 6% L21 Classics sterile	B1 2Shape TS2 n25 6% L21 Classics sterile	Ila	6
60031651	2Shape	B1 2Shape F35 n35 6% L21 Classics sterile	B1 2Shape F35 n35 6% L21 Classics sterile	Ila	6
60031652	2Shape	B1 2Shape F40 n40 4% L21 Classics sterile	B1 2Shape F40 n40 4% L21 Classics sterile	Ila	6
60031653	2Shape	B1 2Shape TS1 n25 4% L25 Classics sterile	B1 2Shape TS1 n25 4% L25 Classics sterile	Ila	6
60031654	2Shape	B1 2Shape TS2 n25 6% L25 Classics sterile	B1 2Shape TS2 n25 6% L25 Classics sterile	Ila	6
60031655	2Shape	B1 2Shape F35 n35 6% L25 Classics sterile	B1 2Shape F35 n35 6% L25 Classics sterile	Ila	6
60031656	2Shape	B1 2Shape F40 n40 4% L25 Classics sterile	B1 2Shape F40 n40 4% L25 Classics sterile	Ila	6
60031657	2Shape	B1 2Shape TS1 n25 4% L31 Classics sterile	B1 2Shape TS1 n25 4% L31 Classics sterile	Ila	6
60031658	2Shape	B1 2Shape TS2 n25 6% L31 Classics sterile	B1 2Shape TS2 n25 6% L31 Classics sterile	Ila	6
60031659	2Shape	B1 2Shape F35 n35 6% L31 Classics sterile	B1 2Shape F35 n35 6% L31 Classics sterile	Ila	6
60031660	2Shape	B1 2Shape F40 n40 4% L31 Classics sterile	B1 2Shape F40 n40 4% L31 Classics sterile	Ila	6
60031661	REMOVER	B1 MicroMega Remover L19 n30 7% Classics	B1 MicroMega Remover L19 n30 7% Classics	Ila	6
60031662	REMOVER	B1 MicroMega Remover L23 n30 7% Classics	B1 MicroMega Remover L23 n30 7% Classics	Ila	6
60031663	One RECI	B1 MicroMega One RECI n20 4% L21 Sterile	B1 MicroMega One RECI n20 4% L21 Sterile	Ila	6
60031664	One RECI	B1 MicroMega One RECI n25 4% L21 Sterile	B1 MicroMega One RECI n25 4% L21 Sterile	Ila	6
60031665	One RECI	B1 MicroMega One RECI n25 6% L21 Sterile	B1 MicroMega One RECI n25 6% L21 Sterile	Ila	6
60031666	One RECI	B1 MicroMega One RECI n35 4% L21 Sterile	B1 MicroMega One RECI n35 4% L21 Sterile	Ila	6
60031667	One RECI	B1 MicroMega One RECI n45 4% L21 Sterile	B1 MicroMega One RECI n45 4% L21 Sterile	Ila	6
60031668	One RECI	B1 MicroMega One RECI n20 4% L25 Sterile	B1 MicroMega One RECI n20 4% L25 Sterile	Ila	6
60031669	One RECI	B1 MicroMega One RECI n25 4% L25 Sterile	B1 MicroMega One RECI n25 4% L25 Sterile	Ila	6
60031670	One RECI	B1 MicroMega One RECI n25 6% L25 Sterile	B1 MicroMega One RECI n25 6% L25 Sterile	Ila	6
60031671	One RECI	B1 MicroMega One RECI n35 4% L25 Sterile	B1 MicroMega One RECI n35 4% L25 Sterile	Ila	6
60031672	One RECI	B1 MicroMega One RECI n45 4% L25 Sterile	B1 MicroMega One RECI n45 4% L25 Sterile	Ila	6
60031673	One RECI	B1 MicroMega One RECI n20 4% L31 Sterile	B1 MicroMega One RECI n20 4% L31 Sterile	Ila	6
60031674	One RECI	B1 MicroMega One RECI n25 4% L31 Sterile	B1 MicroMega One RECI n25 4% L31 Sterile	Ila	6
60031675	One RECI	B1 MicroMega One RECI n25 6% L31 Sterile	B1 MicroMega One RECI n25 6% L31 Sterile	Ila	6
60031676	One RECI	B1 MicroMega One RECI n35 4% L31 Sterile	B1 MicroMega One RECI n35 4% L31 Sterile	Ila	6
60031677	One RECI	B1 MicroMega One RECI n45 4% L31 Sterile	B1 MicroMega One RECI n45 4% L31 Sterile	Ila	6

Micro-Mega SA
12 rue du Tunnel
25000 BESANCON
France

GMED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux dénombrés le 12 mai 2021

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed on May 12, 2021



DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

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REFERENCE	FAMILY	DESIGNATION	CLASS	FILES
60030017	One Curve	B5 MicroMega One Curve mini n25 4% L21 Sterile	Ila	6
60030018	One Curve	B5 MicroMega One Curve mini n25 6% L21 Sterile	Ila	6
60030019	One Curve	B5 MicroMega One Curve mini n35 4% L21 Sterile	Ila	6
60030020	One Curve	B5 MicroMega One Curve mini n45 4% L21 Sterile	Ila	6
60030021	One Curve	B5 MicroMega One Curve mini n25 4% L25 Sterile	Ila	6
60030022	One Curve	B5 MicroMega One Curve mini n25 6% L25 Sterile	Ila	6
60030023	One Curve	B5 MicroMega One Curve mini n35 4% L25 Sterile	Ila	6
60030024	One Curve	B5 MicroMega One Curve mini n45 4% L25 Sterile	Ila	6
60030025	One Curve	B5 MicroMega One Curve mini n25 4% L31 Sterile	Ila	6
60030026	One Curve	B5 MicroMega One Curve mini n25 6% L31 Sterile	Ila	6
60030027	One Curve	B5 MicroMega One Curve mini n35 4% L31 Sterile	Ila	6
60030028	One Curve	B5 MicroMega One Curve mini n45 4% L31 Sterile	Ila	6
60030029	One Curve	B4 MicroMega One Curve mini n25 4% L25 Procedure	Ila	6
60030030	One Curve	B5 MicroMega One Curve mini n25 6% L25 Procedure	Ila	6
60030031	One Curve	B4 MicroMega One Curve mini n35 4% L25 Procedure	Ila	6
60030032	One Curve	B4 MicroMega One Curve mini n45 4% L25 Procedure	Ila	6
60030033	One Curve	B4 MicroMega One Curve mini L21 Assorted Sterile	Ila	6
60030034	One Curve	B4 MicroMega One Curve mini L25 Assorted Sterile	Ila	6
60030035	One Curve	B4 MicroMega One Curve mini L31 Assorted Sterile	Ila	6
60029878	One RECI	B5 MicroMega One RECI N20 4% L21 STERILE	Ila	6
60029879	One RECI	B5 MicroMega One RECI N25 4% L21 STERILE	Ila	6
60029880	One RECI	B5 MicroMega One RECI N25 6% L21 STERILE	Ila	6
60029881	One RECI	B5 MicroMega One RECI N35 4% L21 STERILE	Ila	6
60029882	One RECI	B5 MicroMega One RECI N45 4% L21 STERILE	Ila	6
60029883	One RECI	B5 MicroMega One RECI N20 4% L25 STERILE	Ila	6
60029884	One RECI	B5 MicroMega One RECI N25 4% L25 STERILE	Ila	6
60029885	One RECI	B5 MicroMega One RECI N25 6% L25 STERILE	Ila	6
60029886	One RECI	B5 MicroMega One RECI N35 4% L25 STERILE	Ila	6
60029887	One RECI	B5 MicroMega One RECI N45 4% L25 STERILE	Ila	6
60029888	One RECI	B5 MicroMega One RECI N20 4% L31 STERILE	Ila	6
60029889	One RECI	B5 MicroMega One RECI N25 4% L31 STERILE	Ila	6
60029890	One RECI	B5 MicroMega One RECI N25 6% L31 STERILE	Ila	6
60029891	One RECI	B5 MicroMega One RECI N35 4% L31 STERILE	Ila	6
60029892	One RECI	B5 MicroMega One RECI N45 4% L31 STERILE	Ila	6
60029893	One RECI	B5 MicroMega One RECI N20 4% L25 Procedure Pack	Ila	6
60029894	One RECI	B4 MicroMega One RECI N25 4% L25 Procedure Pack	Ila	6
60029895	One RECI	B5 MicroMega One RECI N25 6% L25 Procedure Pack	Ila	6
60029896	One RECI	B4 MicroMega One RECI N35 4% L25 Procedure Pack	Ila	6
60029897	One RECI	B4 MicroMega One RECI N45 4% L25 Procedure Pack	Ila	6
60029898	One RECI	B5 MicroMega One RECI L21 Assorted Sterile	Ila	6
60029899	One RECI	B5 MicroMega One RECI L25 Assorted Sterile	Ila	6
60029900	One RECI	B5 MicroMega One RECI L31 Assorted Sterile	Ila	6
60031528	Revo-S+	P2 Revo-S+ SC2 SU L25	Ila	6
60031529	Revo-S+	P3 Revo-S+ SC1 SC2 SU L21	Ila	6
60031530	Revo-S+	P3 Revo-S+ SC1 SC2 SU L21, L25	Ila	6
60031531	Revo-S+	P3 Revo-S+ SC1 SC2 SU L21, L31	Ila	6
60031532	Revo-S+	P6 Revo-S+ SC1 L21	Ila	6
60031533	Revo-S+	P6 Revo-S+ SC2 L21	Ila	6
60031534	Revo-S+	P6 Revo-S+ SC2 L25	Ila	6
60031535	Revo-S+	P6 Revo-S+ SC2 L31	Ila	6
60031536	Revo-S+	P6 Revo-S+ SU L21	Ila	6
60031537	Revo-S+	P6 Revo-S+ SU L25	Ila	6
60031538	Revo-S+	P6 Revo-S+ SU L31	Ila	6

Pour le compte de Micro-Mega SA / On behalf of Micro-Mega SA
Stéphane CLAUDE
Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

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DISPOSITIFS MEDICAUX DESTINES A L'ART DENTAIRE ET A LA CHIRURGIE / MEDICAL DEVICES FOR DENTAL ART AND SURGERY			TECHNICAL	
REFERENCE	FAMILY	DESIGNATION	CLASS	FILES
PRESF-250-017-0023	PreSAF	B5 PreSAF FLARE #025 .09 17mm	Ila	6
PRESF-140-021-0024	PreSAF	B5 PreSAF GLIDE #014 .03 21mm	Ila	6
PRESF-140-025-0025	PreSAF	B5 PreSAF GLIDE #014 .03 25mm	Ila	6
PRESF-140-029-0026	PreSAF	B5 PreSAF GLIDE #014 .03 29mm	Ila	6
PRESF-210-021-0027	PreSAF	B5 PreSAF PREP #021 .05 21mm	Ila	6
PRESF-210-025-0028	PreSAF	B5 PreSAF PREP #021 .05 25mm	Ila	6
PRESF-210-029-0029	PreSAF	B5 PreSAF PREP #021 .05 29mm	Ila	6
PRESF-210-000-0030	PreSAF	B3 PreSAF PREP PACK L21	Ila	6
PRESF-250-000-0031	PreSAF	B3 PreSAF PREP PACK L25	Ila	6
PRESF-290-000-0032	PreSAF	B3 PreSAF PREP PACK L29	Ila	6

GMED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits le 12 mai 2021

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed on May 12, 2021

Micro-Mega SA
12 rue du Tunnel
25000 BESANCON
France

GMED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits le 12 mai 2021

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed on May 12, 2021



DECLARATION CE DE CONFORMITE

CE DECLARATION OF CONFORMITY

Micro-Mega SA certifie que les produits suivants sont conformes à l'annexe I et VII de la directive 93/42 CEE relative aux dispositifs médicaux, en tenant compte de toutes les normes harmonisées européennes applicables et aux transpositions en droit national de chaque état et que son système d'assurance qualité, selon l'annexe II excluant le point 4 de la directive 93/42 CEE, est approuvé (Attestation CE n°8881 délivrée par l'organisme notifié GMED).

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DISPOSITIFS MEDICAUX DESTINES A L'ART DENTAIRE ET A LA CHIRURGIE / MEDICAL DEVICES FOR DENTAL ART AND SURGERY			TECHNICAL	
REFERENCE	FAMILY	DESIGNATION	CLASS	FILES
PR0120720AA	Absolute	B5 Absolute Access n25 9% L17 sterile	Ila	6
PR0120721AG	Absolute	B5 Absolute Glide n14 3% L21 sterile	Ila	6
PR0120725AG	Absolute	B5 Absolute Glide n14 3% L25 sterile	Ila	6
PR0120729AG	Absolute	B5 Absolute Glide n14 3% L29 sterile	Ila	6
PR012421AB1	Absolute	B5 Absolute Shaper AB1 n25 6% L21 sterile	Ila	6
PR012421AB2	Absolute	B5 Absolute Shaper AB2 n25 4% L21 sterile	Ila	6
PR012425AB2	Absolute	B5 Absolute Shaper AB2 n25 4% L25 sterile	Ila	6
PR012431AB2	Absolute	B5 Absolute Shaper AB2 n25 4% L31 sterile	Ila	6
PR012421AB3	Absolute	B5 Absolute Shaper AB3 n25 6% L21 sterile	Ila	6
PR012425AB3	Absolute	B5 Absolute Shaper AB3 n25 6% L25 sterile	Ila	6
PR012431AB3	Absolute	B5 Absolute Shaper AB3 n25 6% L31 sterile	Ila	6
PR012421AB30	Absolute	B5 Absolute Shaper Apical n30 6% L21 sterile	Ila	6
PR012425AB30	Absolute	B5 Absolute Shaper Apical n30 6% L25 sterile	Ila	6
PR012431AB30	Absolute	B5 Absolute Shaper Apical n30 6% L31 sterile	Ila	6
PR012421AB35	Absolute	B5 Absolute Shaper Apical n35 6% L21 sterile	Ila	6
PR012425AB35	Absolute	B5 Absolute Shaper Apical n35 6% L25 sterile	Ila	6
PR012431AB35	Absolute	B5 Absolute Shaper Apical n35 6% L31 sterile	Ila	6
PR012421AB40	Absolute	B5 Absolute Shaper Apical n40 6% L21 sterile	Ila	6
PR012425AB40	Absolute	B5 Absolute Shaper Apical n40 6% L25 sterile	Ila	6
PR012431AB40	Absolute	B5 Absolute Shaper Apical n40 6% L31 sterile	Ila	6
PR012421ASP	Absolute	B5 Absolute Shaper Pack L21 sterile	Ila	6
PR012425ASP	Absolute	B5 Absolute Shaper Pack L25 sterile	Ila	6
PR012431ASP	Absolute	B5 Absolute Shaper Pack L31 sterile	Ila	6

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Stéphane CLAUDE
Directeur Général Délégué / Delegated General Manager

Besancon, le / the 2021-04-22

