DICHIARAZIONE DI CONFORMITÀ UE
DECLARATION OF CONFORMITY EU

La società KALTEK S.r.l, con sede legale e operativa in Via Liguria, 29 – 35020 SAONARA (PD)/Italia
KALTEK S.r.l. with legal and operational headquarters in Via Liguria, 29 – 35020 SAONARA (PD)/Italy

DICHIARA
sotto la propria totale responsabilità,

DECLARES
under its own responsibility,

che i dispositivi medici denominati:
that the medical devices named:

PADELLA / *BED PAN*
REF. 0645 - 16 200 21 – 03321 (Basic UDI-DI: 805551056064 5YJ)

PADELLA CON SCATOLA / *BED PAN WITH BOX*
REF. 2483 (Basic UDI-DI: 8055510562483YW)

PADELLA PER BAMBINO / *BED PAN FOR CHILDREN*
REF. 2990 (Basic UDI-DI 80555105629 90ZL)

PADELLA PESANTE / *HEAVY BED PAN*
REF. 3544 (Basic UDI-DI: 8055510563544YY)

PADELLA CON COPERCHIO / *BED PAN WITH LID*
REF. 4579 - 16 200 21D (Basic UDI-DI: 805551056457 9ZS)

PADELLA CON MANICO ERGONOMICO / *BED PAN WITH ERGONOMIC HANDLE*
REF. 0949 - 16 200 21E (Basic UDI-DI: 805551056094 9Z9)

COPERCHIO PER PADELLA / *LID FOR PAD BAN*
REF. 0665 - 16 200 21CE (Basic UDI-DI: 805551056066 5YQ)

PADELLA MONOUSO IN CARTONE / *DISPOSABLE PAPER PULP BED PAN*
REF. 2020 (Basic UDI-DI: 8055510562020XJ)

classe di rischio I non sterile, in accordo alla regola 1 dell'Allegato VIII del Regolamento UE 2017/745
risk class I not sterile, rule No. 1 according to the Annex VIII of the Regulation (EU) 2017/745

- sono conformi ai requisiti essenziali e alle disposizioni del Regolamento (UE) 2017/745 e ss.mm.ii. come da Fascicolo Tecnico n. FT003KT (archiviato presso la Kaltek);
  comply with the essential requirements of Regulation (EU) 2017/745 and its amendments as described in the Technical File No. FT003KT (archived in Kaltek headquarters);

- sono fabbricati in accordo al Fascicolo Tecnico, che soddisfa i requisiti di cui all'Allegato II e III del sopra citato Regolamento.
  are manufactured according to the Technical File which complies with the requirements of Annex II and III of that Regulation.

Padova, 07/10/2021

kaltek srl
Il legale rappresentante
Cortelazzo Dr. Lorenzo

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CE MARK

ZIANA
INDUSTRIES

EC DECLARATION OF CONFORMITY

We, M/s. **Ziana Industries, Islam Nagar Road, Pacca Garah, Sialkot-51310-Pakistan** hereby declare that we fall within manufacturers of Class-I devices and the devices produced by us i.e.

REF	FR	EN
28 400 08	MIROIR LARYNGIEN 08 MM K 00	LARYNGEAL MIRROR
28 400 10	MIROIR LARYNGIEN 10 MM K 0	LARYNGEAL MIRROR
28 400 12	MIROIR LARYNGIEN 12 MM K 1	LARYNGEAL MIRROR
28 400 14	MIROIR LARYNGIEN 14 MM K 2	LARYNGEAL MIRROR
28 400 16	MIROIR LARYNGIEN 16 MM K 3	LARYNGEAL MIRROR
28 400 18	MIROIR LARYNGIEN 18 MM K 4	LARYNGEAL MIRROR
28 400 20	MIROIR LARYNGIEN 20 MM K 5	LARYNGEAL MIRROR
28 400 22	MIROIR LARYNGIEN 22 MM K 6	LARYNGEAL MIRROR
28 400 24	MIROIR LARYNGIEN 24 MM K 7	LARYNGEAL MIRROR
28 400 26	MIROIR LARYNGIEN 26 MM K 8	LARYNGEAL MIRROR
28 400 28	MIROIR LARYNGIEN 28 MM K 9	LARYNGEAL MIRROR
28 400 30	MIROIR LARYNGIEN 30 MM K 10	LARYNGEAL MIRROR
28 401 00	MANCHE A VIS POUR MIROIRS	HANDLE WITH SCREW FOR MIRRORS
29 200 28	DIAPASON C 128	HARTMANN TUNING FORK
29 200 29	DIAPASON C 128 AVEC CURSEURS	HARTMANN TUNING FORK WITH WEIGHT
29 200 56	DIAPASON C 256	HARTMANN TUNING FORK
29 200 57	DIAPASON C 256 AVEC CURSEURS	HARTMANN TUNING FORK WITH WEIGHT
29 200 64	DIAPASON NEUROLOGIQUE 64 HZ	NEUROLOGICAL TUNING FORK
29 205 12	DIAPASON C 512	HARTMANN TUNING FORK
29 210 24	DIAPASON C 1024	HARTMANN TUNING FORK
29 365 00	TIRE COMEDONS DE UNNA EN INOX	UNNA CURETTE
33 430 00	AIMANT OCULAIRE	EYE MAGNET
33 450 00	AIMANT OCULAIRE AVEC LOUPE	EYE MAGNET WITH MAGNIFYING GLASS
33 500 00	PRECELLE AVEC LOUPE	SPLINTER WITH MAGNIFYING GLASS
33 600 00	PINCE A TIQUES	TICK TWEEZER
36 001 14	STYLET OLIVAIRE SIMPLE 14 CM	PROBE WITH KNOB
36 002 14	STYLET OLIVAIRE DOUBLE 14 CM	PROBE WITH KNOB DOUBLE

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36 052 00	STYLET PORTE-COTON	PROBE WITH THREAD
41 581 00	MARTEAUX REFLEXES BABINSKY	BABINSKY REFLEX HAMMER
41 581 10	MARTEAUX REFLEXES DE VERNON	VERNON REFLEX HAMMER
41 581 20	MARTEAUX REFLEXES BUCK	BUCK REFLEX HAMMER
41 581 30	MARTEAUX REFLEXES TAYLOR	TAYLOR REFLEX HAMMER
43 960 00	STETHOSCOPE DE PINARD EN BOIS	PINARD STETHOSCOPE IN WOOD
47 310 00	CISAILLE A PLATRE DE STILLE	STILLE PLASTER SHEARS
47 310 21	CISAILLE A PLATRE 21 CM	PLASTER SHEARS
47 310 23	CISAILLE A PLATRE DE BRUN	BRUN PLASTER SHEARS
47 320 00	ECARTEUR A PLATRE DE HENNING	HENNING PLASTER SPREADER
C1 001 11	CISEAUX MOUSSE DROITS 11,5 CM	OPERATING SCISSORS B/B STRAIGHT
C1 001 14	CISEAUX MOUSSE DROITS 14CM	OPERATING SCISSORS B/B STRAIGHT
C1 001 16	CISEAUX MOUSSE DROITS 16 CM	OPERATING SCISSORS B/B STRAIGHT
C1 001 18	CISEAUX MOUSSE DROITS 18 CM	OPERATING SCISSORS B/B STRAIGHT
C1 002 14	CISEAUX DAUPHINS DROITS 14 CM	OPERATING SCISSORS B/S STRAIGHT
C1 002 16	CISEAUX DAUPHINS DROITS 16 CM	OPERATING SCISSORS B/S STRAIGHT
C1 002 18	CISEAUX DAUPHINS DROITS 18 CM	OPERATING SCISSORS B/S STRAIGHT
C1 003 14	CISEAUX POINTUS DROITS 14 CM	OPERATING SCISSORS S/S STRAIGHT
C1 003 16	CISEAUX POINTUS DROITS 16 CM	OPERATING SCISSORS S/S STRAIGHT
C1 011 14	CISEAUX MOUSSE COURBES 14 CM	OPERATING SCISSORS B/B CURVED
C1 021 14	CISEAUX DAUPHINS COURBES 14 CM	OPERATING SCISSORS B/S CURVED
C1 031 14	CISEAUX POINTUS COURBES 14 CM	OPERATING SCISSORS S/S CURVED
C1 040 14	CISEAUX METZENBAUM DROITS 14 CM	METZENBAUM SCISSORS STRAIGHT
C1 041 14	CISEAUX METZEMBAUM COURBES 14CM	METZENBAUM SCISSORS CURVED
C1 050 16	CISEAUX MAYO DROITS 16 CM	MAYO SCISSORS STRAIGHT
C1 051 16	CISEAUX MAYO COURBES 16 CM	MAYO SCISSORS CURVED
C1 051 18	CISEAUX MAYO COURBES 18 CM	MAYO SCISSORS CURVED
C1 060 10	CISEAUX IRIDECTOMIE DROITS 10 CM	IRIS SCISSORS STRAIGHT
C1 060 11	CISEAUX IRIDECTOMIE DROITS 11 CM	IRIS SCISSORS STRAIGHT
C1 061 10	CISEAUX IRIDECTOMIE COURBES 10 CM	IRIS SCISSORS CURVED
C1 061 11	CISEAUX IRIDECTOMIE COURBES 11 CM	IRIS SCISSORS CURVED
C1 100 14	CISEAUX DE LISTER 14 CM	LISTER SCISSORS
C1 100 16	CISEAUX DE LISTER 16CM	LISTER SCISSORS
C1 100 18	CISEAUX DE LISTER 18CM	LISTER SCISSORS

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C1 110 10	CISEAUX A ONGLES DROITS 10 CM	NAILS SCISSORS STRAIGHT
C1 111 10	CISEAUX A ONGLES COURBES 10 CM	NAILS SCISSORS CURVED
C1 150 11	CISEAUX SPENCER DROITS 11 CM	SPENCER SCISSORS
C1 150 13	CISEAUX SPENCER DROITS 13 CM	SPENCER SCISSORS
C1 165 16	CISEAUX DE KELLY DROITS 16 CM	KELLY SCISSORS STRAIGHT
C1 200 03	MANCHE DE BISTOURIS NR.3	SCALPEL HANDLE
C1 200 04	MANCHE DE BISTOURIS NR.4	SCALPEL HANDLE
C1 200 50	SONDE CANNELEE, 14CM	DIRECTOR & TONGUE TIE
C1 300 14	PINCE A DISSEQUER S.G. 14 CM	DISSECTING FORCEPS
C1 430 14	PINCE COUDEE TROELSCH 14 CM SG	TROELSCH FORCEPS WITHOUT TEETH
C1 432 14	PINCE COUDEE TROELSCH 14 CM AG	TROELSCH FORCEPS WITH TEETH
C1 440 15	PINCE LONDON COLLEGE 15 CM	LONDON COLLEGE TWEEZER
C1 450 12	PINCE DISSEC.SEMKIN SS GR.12 CM	SEMKIN DISSECTION FORCEPS
C1 500 09	PINCE A ECHARDES 9 CM	FEILCHENFELD FORCEPS
C2 000 14	PINCE KOCHER DROITE S.G. 14 CM	ROCHESTER PEAN FORCEPS STRAIGHT WITHOUT TEETH
C2 000 16	PINCE KOCHER DROITE S.G. 16 CM	ROCHESTER PEAN FORCEPS STRAIGHT WITHOUT TEETH
C2 010 14	PINCE DE PEAN DROITE 14 CM	MURPHY PEAN FORCEPS
C2 050 14	PINCE KOCHER DROITE A.G. 14 CM	ROCHESTER PEAN FORCEPS STRAIGHT WITH TEETH
C2 050 16	PINCE KOCHER DROITE A.G. 16 CM	ROCHESTER PEAN FORCEPS STRAIGHT WITH TEETH
C2 051 14	PINCE KOCHER COURBE S.G. 14 CM	ROCHESTER PEAN FORCEPS CURVED WITHOUT TEETH
C2 051 16	PINCE KOCHER COURBE S.G. 16 CM	ROCHESTER PEAN FORCEPS CURVED WITHOUT TEETH
C2 053 14	PINCE KOCHER COURBE A.G. 14 CM	ROCHESTER PEAN FORCEPS CURVED WITH TEETH
C2 053 16	PINCE KOCHER COURBE A.G. 16 CM	ROCHESTER PEAN FORCEPS CURVED WITH TEETH
C2 070 09	PINCE HARTMANN DROITE S.G. 9 CM	HARTMANN FORCEPS STRAIGHT WITHOUT TEETH
C2 080 12	PINCE DE HALSTEAD DROITE S.G. 13 CM	HALSTEAD FORCEPS STRAIGHT WITHOUT TEETH
C2 081 12	PINCE DE HALSTEAD COURBE S.G. 13 CM	HALSTEAD FORCEPS CURVED WITHOUT TEETH
C2 082 12	PINCE DE HALSTEAD DROITE A.G. 13 CM	HALSTEAD FORCEPS STRAIGHT WITH TEETH
C2 083 12	PINCE DE HALSTEAD COURBE A.G. 13 CM	HALSTEAD FORCEPS CURVED WITH TEETH
C2 090 15	PINCE LERICHE DROITE S.G.15 CM	LERICHE FORCEPS STRAIGHT WITHOUT TEETH
C2 091 15	PINCE LERICHE COURBE S.G. 15 CM	LERICHE FORCEPS CURVED WITHOUT TEETH
C2 092 15	PINCE LERICHE DROITE A.G.15 CM	LERICHE FORCEPS STRAIGHT WITH TEETH
C2 093 15	PINCE DE LERICHE COURBE AG15 CM	LERICHE FORCEPS CURVED WITH TEETH

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C2 096 14	PINCE DE KELLY DROITE 14 CM	KELLY FORCEPS STRAIGHT
C2 096 16	PINCE DE KELLY DROITE 16 CM	KELLY FORCEPS STRAIGHT
C2 096 18	PINCE DE KELLY DROITE 18 CM	KELLY FORCEPS STRAIGHT
C2 097 14	PINCE DE KELLY COURBE 14 CM	KELLY FORCEPS CURVED
C2 097 16	PINCE DE KELLY COURBE 16 CM	KELLY FORCEPS CURVED
C2 100 24	PINCE LONGUETTE DROITE 24 CM	MAIR POLYPUS FRENCH FORCEPS STRAIGHT
C2 110 24	PINCE DE CHERON 24 CM	CHERON FORCEPS
C2 200 11	PINCE DE BACKHAUS DE 11 CM	BACKHAUS FORCEPS
C2 200 13	PINCE DE BACKHAUS DE 14CM	BACKHAUS FORCEPS
C2 220 09	PINCE CRABE 9 CM	JONES TOWEL FORCEPS
C2 220 15	PINCE ALLIS 15 CM	ALLIS TISSUE FORCEPS
C2 228 18	PINCE CLAMP INTES.DOYEN DROITE 18 CM	DOYEN INTESTINAL CLAMP FORCEPS STRAIGHT
C2 229 18	PINCE CLAMP INTES. COURBE 18 CM	DOYEN INTESTINAL CLAMP FORCEPS CURVED
C2 240 14	PINCE CRILE DROITE 14 CM	CRILE FORCEPS STRAIGHT
C2 241 14	PINCE CRILE COURBE 14 CM	CRILE FORCEPS CURVED
C2 250 13	PINCE DE TERRIER SS GRIFFE 13 CM	TERRIER FORCEPS
C2 260 15	PINCE MAGILL 15 CM	MAGILL FORCEPS
C2 260 20	PINCE MAGILL 20 CM	MAGILL FORCEPS
C2 260 24	PINCE MAGILL 24 CM	MAGILL FORCEPS
C2 265 13	PINCE A GLISSEMENT HARTMANN 13CM	HARTMANN EAR POLYPUS FORCEPS
C2 280 24	PINCE POZZI DROITE 24CM	POZZI FORCEPS
C2 290 24	PINCE FOERSTER DROITE 24 CM	FOERSTER FORCEPS STRAIGHT
C2 291 24	PINCE FOERSTER COURBE 24 CM	FOERSTER FORCEPS CURVED
C2 300 00	PINCE ADSON SANS GRIFFE 12 CM	ADSON FORCEPS WITHOUT TEETH
C2 302 00	PINCE ADSON AVEC GRIFFE 12 CM	ADSON FORCEPS WITH TEETH
C2 400 13	PINCE DE MICHEL 13CM	MICHEL DOUBLE USE FORCEPS
C3 010 16	PORTE AIGUILLE MAYO HEGAR 16 CM	MAYO HEGAR NEEDLE HOLDER
C3 030 14	PORTE AIGUILLE DE MATHIEU 14 CM	MATTHIEU NEEDLE HOLDER
C3 030 17	PORTE AIGUILLE DE MATHIEU 17 CM	MATTHIEU NEEDLE HOLDER
C3 035 13	PORTE AIGUILLE CRILE-WOOD 13 CM	CRILE-WOOD NEEDLE HOLDER
C3 035 15	PORTE AIGUILLE CRILE-WOOD 15 CM	CRILE-WOOD NEEDLE HOLDER
C4 107 01	ANSE DE BILLEAU PETIT MODELE	BILLEAU LOOP
C4 107 02	ANSE DE BILLEAU MEDIUM	BILLEAU LOOP
C4 107 03	ANSE DE BILLEAU LARGE	BILLEAU LOOP

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C4 200 13	ANSE DE SNELLEN 13.5 CM	SNELLEN LOOP
C5 200 08	PINCE BISHOP-HARMANN 8 CM S/G	BISHOP HARMANN FORCEPS WITHOUT TEETH
C5 420 16	PINCE BRUCELLE DE MIRIAM 16 CM	BRUCELLE MIRIAM FORCEPS
C5 500 02	SPECULUM NASAL DE VACHER 8CM	VACHER NASAL SPECULUM
C8 020 01	SPECULUM DE CUSCO 75 X 32 MM	CUSCO SPECULUM
C8 020 02	SPECULUM DE CUSCO 85 X 35 MM	CUSCO SPECULUM
C8 021 25	SPECULUM DE COLLIN 25 X 110 MM	COLLIN SPECULUM
C8 021 30	SPECULUM DE COLLIN 30X110 MM	COLLIN SPECULUM
C8 021 35	SPECULUM DE COLLIN 35 X 110 MM	COLLIN SPECULUM
C8 021 40	SPECULUM DE COLLIN 40 X 120 MM	COLLIN SPECULUM
CV BM2 99	PORTE AIGUILLES GILLIES 16 CM	GILLIES NEEDLE HOLDER

meet the essential requirement of Directive No. 93/42/EEC dated June 14, 1993. We prepare and maintain technical documentation for each device as required by Annex-VII of the directive 93/42/EEC. We shall maintain these documentations for 5 years from the date of their production. The technical documentation can be made available to the competent authority on demand.

We further declare that we have **designated the person responsible for marketing our above stated devices. Detail of the designated person responsible for marketing (Authorized Representative) is as under**:

Zahid Anwar
EU Representative
Certlink Certification Services
P.zza Cavour 18,
20832 Desio (MB), Italia.

Mr. Zahid Anwar has registered place of business in Italy. He is also already registered with MOH, Italy.

Date of issue: 28/10/2020
Authorized Name & Designation:

Authorized Signature & Company Stamp:

Place of issue: Sialkot-Pakistan
Akif Abbas
Managing Partner

ZIANA INDUSTRIES
MG. PARTNER

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FM Deura & Co.

EC DECLARATION OF CONFORMITY

Date of Issuance 28-07-2021 Valid till 28-07- 2026

FM Deura& Co.
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E-mail: info@fmdeura.com
Web: www.fmdeura.com

Is registered in EUDAMED with SRN number **PK-MF-000010060.**
and Competent Authority ''Swedish Medical Products Agency – Läkemedelsverket'' with diary number 6.6 1-2021-58819.

Hereby declares that EC Representative had been appointed as follow for
Medical Devices (Class I – Reusable)
IBC – Sweden
14564 Norsborg
Stockholm, Sweden
Email: eurep@ibcsweden.eu

We hereby declare that the EC declaration of conformity is issued under the sole responsibility of the FM Deura& Co. as per Article 19 and Annex IV and tends to meet the essential and applicable requirements as per Annex IV under Regulation (EU) 2017/745 [MDR 2017/745 for CE] . Medical Devices attached in Annex A are in conformity with the MDR 2017/745 and relevant harmonized standards and the relevant parts of applicable standards of Official Journal of the European Union, are applied where applicable and presumed to be in conformity with the requirements of ''Risk class I'' of the device in accordance with the rules set out in Annex VIII covered by those standards or parts thereof.

The products manufactured are provided in Annex A of this EC Declaration of conformity. The products declared in Annex A are in compliance to applicable standards and or are harmonized by EU Medical Device Regulation 2017/745 and Swedish Medical Products Agency – Läkemedelsverket. The traceability of the device covered by the EU declaration of conformity are in compliance where appropriate (Quality Management System and UDI protocols, as well as its intended purpose.

We also declare; Products mentioned in Annex A of this declaration are in conformity with applicable general safety and performance requirements given in Annex I of MDR 2017/745 under the conditions of the intended use of the device, Documents will be presented upon request by a Swedish Medical Products Agency – Läkemedelsverket, the indicated therein, FM Deura& Co.will provide that technical documentation in its entirety and summary thereof.

The products manufactured are Reusable - Class I (Non-Sterilized), lower risk products in line with Annex VIII;

The products referred to Annex A are developed with due care in lieu of technical documentation referred to in Annexes II and III of MDR 2017/745 and harmonized standards given in Annex B of this declaration.

To keep the technical documentation, the EU declaration of conformity andrelevant certificates, including any amendments and supplements, issued in accordance with Article 56, availablefor the Swedish Medical Products Agency – Läkemedelsverket for a period of at least 10 years after the last device covered by the EU declaration ofconformity has been placed on the market.

The Basic UDI-DI as referred to in Part C of Annex VI had been established in reference to product in Annex A as per information to be submitted upon the registration of Devices and Economic Operators in accordance with articles 28, 29 and 31.

FM Deura & Co. Proprietor

Annex A

Product List

Declares that products list has been classified as Medical Devices (Class I – Reusable) inclusive of mentioned product variant sis in conformity with the essential requirements, provisions of Medical Device Regulation 2017/745 and Swedish Medical Products Agency – Läkemedelsverket. IBC – Sweden had been appointed as EC Representative for following products.

Sr. No.	Product Group	RISK CLASS	PRODUCT INFORMATION	PRODUCT CODE (FMD)	PRODUCT CODE (COMED)	BASIC UDI-DI
1	Scissors	CLASS 1	UTILITY SCISSORS 7-1/2" (RED HANDLE)	01US01	29 102 40	896400314201US01743G
			UTILITY SCISSORS 7-1/2" (BLUE HANDLE)	01US02	29 102 41	
			UTILITY SCISSORS 7-1/2" (YELLOW HANDLE)	01US03	29 102 42	
			UTILITY SCISSORS 7-1/2" (BLACK HANDLE)	01US04	29 102 45	
			MAYO SCISSORS 14CM STARIGHT	02US11	C1 050 14	
			MAYO SCISSORS 14CM CURVED	02US12	C1 051 14	
			KELLY SCISSORS 16CM STRAIGHT	03US21	C1 165 16	
			IRIS SCISSORS 11CM STRAIGHT	04US31	C1 060 11	
			ISIS SCISSORS 11CM CURVED	04US32	C1 061 11	
			SPENCER/STICH SCISSORS 11CM STRAIGHT	05US41	C1 150 11	

FM Deura & Co. Proprietor

FM

FM Deura & Co.

2	Forceps	CLASS 1	POZZI FORCEPS 24CM STRAIGHT	06GF75	C2 280 24	896400314206GF750003A
			BANGOLEA FORCEPS STRAIGHT 20CM	07GF85	C2 270 20	
			MICHEL DOUBLE USE FORCEPS 13 cm	08GF95	C2 400 13	
			FIELCHENFELD FORCEPS 09CM	09GF101	C1 500 09	
			FIELCHENFELD FORCEPS 11CM	09GF102	C1 500 11	
			ADSON FORCEPS 12CM NO TEETH	10GF125	C2 300 00	
			MAYO HEGAR NEEDLE HOLDER 14CM	11GF151	C3 010 14	
3	Operating Scissors	CLASS 1	OPERATING SCISSORS B/B 14 CM STRAIGHT	12OS201	C1 001 14	896400314212OS201224HX
4	Tweezers	CLASS 1	LONDON COLLEGE TWEEZERS 14 CM	12GT225	C1 440 15	896400314213GT225250G2
			DISSECTING FORCEPS 14CM 1X2 TEETH	12GT235	C1 400 14	
5	Vaginal Specula	CLASS 1	COLLIN VAGINAL SPECULUM 38 x 120	14VS251	C8 021 38	896400314214VS251274RQ
			COLLIN VAGINAL SPECULUM 40 x 120	14VS252	C8 021 40	
			CUSCO VAGINAL SPECULUM LARGE 100 x 37 cm	14VS260	C8 020 03	
6	Shears	CLASS 1	BRUN PLASTER SHEARS 23CM	15GS275	47 310 23	896400314215GS275300JC

FM Deura & Co.
Proprietor

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FM Deura & Co.

Annex B

The products mentioned in Annex A of this declaration are hereby declared in conformity with applicable harmonized standard mentioned below.

Standards	Description
Medical devices-Application of risk management to medical Devices	ISO 14971
Medical Device Regulation (MDR)	Regulation (EU) 2017/745
Medical devices-Quality management systems-Requirements for regulatory purposes.	EN ISO 13485: 2016
Biological evaluation of medical devices-Part 1: Evaluation and testing	ISO10993-1
Biological evaluation of medical devices -Part 2: Animal welfare requirements	ISO10993-2
Biological evaluation of medical Devices-Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	EN ISO10993-3
Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol	ISO 15223-2:2010
Graphical Symbols for Use in the Labeling of Medical Devices	ISO 15223-1
Guide line for authorized representatives	MEDDEV 2.5. /10
Medical device classification	MEDDEV 2.4/1
Evaluation of clinical data- guide for manufacturer and notified bodies	MEDDEV 2.7.1 Appendix-1
Medical device vigilance system	MEDDEV 2.12.1
Standard Specification for Stainless Steel Billet, Bar, and Wire forSurgical Instruments	ASTM-F899
Surgical Instruments – Metallic Materials – Part 1: Stainless Steel	ISO 7153-1
Sterilization of Health care products	ISO 17665-1
Competent Authority (Swedish Medical Products Agency – Läkemedelsverket)	Medical Devices Act HSLF-FS2021:32and the Swedish Medicine Agency`sRegulations, LVFS 2003:11 or LVFS 2001:7. 2021:43

FM Deura & Co.
Proprietor

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HALLMARK SURGICO

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: +92-52-3256450 EMAIL: hallmark@brain.net.pk

EC DECLARATION OF CONFIRMITY.

WE M/S **HALLMARK SURGICO**. HAVING ADDRESS P.O.BOX 205, KHADIM ALI ROAD, **SIALKOT.PAKISTAN.BEING** THE MANUFACTURERS OF **LARYNGOSCOPES BOTH CONVENTIONAL AND FIBEROPTIC, SURGICAL INSTRUMENTS** AND **SCISSORS** OF ALL SORTS, **DENTAL INSTRUMENTS, HOSPITAL** STAINLESS STEEL INSTRUMENTS AND EQUIPMENTS.

WE HEREBY DECLARE THAT THE MATERIAL USED IN OUR PRODUCTS IS NOT HARMFUL TO ANY PART OF HUMAN BODY. WE ALSO CERTIFY THAT OUR PRODUCTS WHICH ARE IN **CLASS ONE** OF **MEDICAL DEVICES** OF EUROPEAN UNION **MEDICAL DIRECTIVE** MEETS ALL THE REQUIREMENTS FOR **CLASS-1 MEDICAL DEVICES (ARTICLE 11(5), ANNEX V11 SECTION** 3, **COUNCIL DIRECTIVE 93/42/EEC**, REGARDING HEALTH AND SAFETY.

REGARDS

For & on behalf of
HALLMARK SURGICO.
Nadeem Aftab
Partner

NADEEM AFTAB.
SALES EXECUTIVE/PARTNER.
HALLAMRK SURGICO.
DATED:23-02-2018

EU Declaration of Conformity

Manufacturer: Goodwood Medical Care Ltd

Address: 1-2 Floor, 3-919, Yongzheng Street, Jinzhou District, Dalian Liaoning, China

Whose single Authorized Representative:
CMC Medical Devices & Drugs S.L.
Address: C/ Horacio Lengo No18, CP 29006, Málaga, Spain

WE, AS THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.
HEREWITH DECLARE THAT /

the STATE medical device:/	Tongue Depressors
Model:/	GW-1102/GW-1106/GW-/1108/GW-1110
GMDN Code:/	14066
Basic UDI:_	697312826GW010DT
Of class:/	I, RULE 5(5.1/1) according to Annex VIII of Regulation EU 2017/745(MDR)

meets the provisions of Regulation EU 2017/745(MDR) and its transportations in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

Applicable harmonized standards are: /
EN ISO13485:2016/EN ISO14971:2019/EN 62366-1:2015/EN 1041: 2008+A1:2013/EN ISO 15223-1:2016/ISO 10993-1:2018/EN ISO10993-5:2009/EN ISO 10993-10:2013

Dalian, 2021-05-20

CEO

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

EU-Konformitätserklärung
gemäß Artikel 19 Verordnung 2017/745 (MDR)

Dokument	Revision	Freigabe	Gültig ab	Seite
TD 1.4-009	1	06.07.2021	06.07.2021	1 von 1

Kontaktdaten des Herstellers:

Friedrich Huber aeronova GmbH & Co. KG
Sobrigauer Weg 4
D-01257 Dresden
Tel.: 0049 - (0)351 - 27046-12
Fax: 0049 - (0)351 - 27046-16
E-Mail: info@aeronova.de
SRN: DE-MF-000009163

Diese Konformitätserklärung wird unter alleiniger Verantwortung des Herstellers ausgestellt.

Produktbezeichnung:

Produkt- u. Handelsname: Silikonspray
Produktcode: 79 002
Zweckbestimmung:
- Schmierung beweglicher Teil und wirksamer Korrosionsschutz
- gleichmäßige Filmbildung
- verhindert das Verkleben medizinischer Instrumente mit der Schleimhaut

Basis-UDI-DI gemäß Anhang VI Teil C: 42700026383SilikonsprayV5
Risikoklasse gemäß Anhang VIII: I

Folgende Normen/Spezifikationen wurden angewandt:

DIN EN ISO 13485 Medizinprodukte – Qualitätsmanagementsysteme – Anforderungen für regulatorische Zwecke
DIN EN ISO 14971 Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte
DIN EN 1041 Bereitstellung von Informationen durch den Hersteller von Medizinprodukten
DIN EN 15233 Methodik zur Bewertung der funktionalen Sicherheit von Schutzsystemen für explosionsgefährdete Bereiche
DIN EN 62366 Medizinprodukte - Teil 1: Anwendung der Gebrauchstauglichkeit auf Medizinprodukte

Wir bestätigen, dass die Produkte den anwendbaren grundlegenden Sicherheits- und Leistungsanforderungen nach der Verordnung über Medizinprodukte (EU) 2017/745 entsprechen.

HUBER
Geschäftsführer

Dresden, 06.07.2021
Ort, Datum

Name, Unterschrift Geschäftsführer

Manufacturer's Logo

Medimel
Disposable Medical Products

DECLARATION of CONFORMITY E.U.

We are solely responsible for declaring that the Medical Devices mentioned in this statement are of Low-Risk Class (Class I) and comply with the requirements of the European Regulation 2017/745 and where appropriate, the standards and legislation referred to.

MANUFACTURER:	MEDIMEL IKE
SRN:	
SEAT ADDRESS:	DERVENAKION 9 KORYDALLOS
E-MAIL:	info@medimel.gr
TELEPHONE:	2169000630

COMPETENT AUTHORITY:	EOF GREECE
CONTACT DETAILS:	Address: MESOGEION 284,XALANDRI Telephone:2132040200 Web site:

LIST OF PRODUCTS COVERED BY THIS DECLARATION

No	PRODUCT	CODE	UDI-DI	INTENDED USE	RULE
	24HRS GRADUATED URINE 2.5lt CONTAINER	200702	5207219CONSIMABLSXC	24 HOUR URINE COLLECTION FOR DIAGNOSTIC TESTS	1.1

APPLIED STANDARDS &LEGAL REQUIREMENTS

ISO 13485:2016

CE

	APPROVAL
NAME:	KINIGOPOULOS ATHANASIOS
POSITION:	GENERAL MANAGER
PLACE:	KORYDALLOS ATHENS
DATE:	29/06/2021
SIGN:	 KINIGOPOULOS ATHANASIOS

DiagrammHalbach
Medizintechnik

EG-Konformitätserklärung / EC-Declaration of Conformity

gem. Anhang VII der Richtlinie 93/42/EWG Medizinprodukte (inklusiv Richtlinie 2007/47/EG)
according to Appendix VII of the Directive 93/42/EEC Medical Devices (including directive 2007/47/EC)

Wir / We

Diagramm Halbach GmbH & Co. KG
Am Winkelstück 14
D-58239 Schwerte

erklären hiermit, daß das/die Produkt/e
declare that the products

Bezeichnung / Term: **Elektroden Spray Clinical**
Artikelnummmer / item number

848333 Elektrodenspray Cinical 250 ml

- **den einschlägigen Bestimmungen der Richtlinie 93/42/EWG (für Medizinprodukte inklusive Änderungen und Ergänzungen der Richtlinie 2007/47/EG) entsprechen.**
  corresponds to the relevant regulations of the Directive 93/42/EEC (Medical Devices including changes and additions of the directive 2007/47/EC).

- **gemäß Anhang IX "Klassifizierungskriterien" der Richtlinie 93/42EWG Abs. III Ziffer 1.1 Regel 1, Klasse I Produkte sind.**
  are Class I products according the rules of classification to Annex IX, par. III, figure 1.1 rule 1 of the Directive 93/42/EEC (Medical Devices).

07.04.2016
Datum / date

i. A. Drilling
Qualitätsmanager / quality manager:

PARKER LABORATORIES, INC.

Declaration of Conformity

Manufacturer:	Parker Laboratories, Inc. 286 Eldridge Road Fairfield, NJ 07004 USA Single Registration Number (SRN): US-MF-000013857
Description:	Nonsterile ultrasound gels, creams, lotions
Classification:	Class I Non-measuring, non-sterile per REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 Annex VIII Chapter 3 Rule 1
EC Representative:	Parker Laboratories BV Bedrijvenpark Twente 305 7602 KL Almelo The Netherlands Single Registration Number (SRN): NL-AR-000012618
Products:	See attached product list
Intended Use:	Non-sterile ultrasound products are intended for use with commercially available ultrasound devices to couple sound waves between a patient and an ultrasound transducer. They are intended for use on intact skin for noninvasive diagnostic and therapeutic ultrasound procedures.

These products are manufactured in compliance with the following standards:

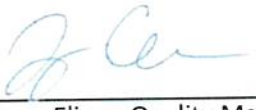
- ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- EN 1041:2008 Information Supplied by the Manufacturer with Medical Devices
- ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices
- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity
- ISO 10993-10:2012 Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization

PARKER LABORATORIES, INC.

Parker Laboratories, Inc., being a manufacturer of medical devices sold within the European Union, hereby declares that the products covered by this declaration meet the relevant provisions of the European Regulation (EU) 2017/745 for Medical Devices and the General Safety and Performance Requirements listed in Annex I.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer, Parker Laboratories, Inc.

Signature:



15 Oct 2021

Larry Elisca, Quality Manager
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

Date

PARKER LABORATORIES, INC.

Product List – Non-sterile Ultrasound Products

Product Description	Product Refs	Basic UDI-DI
Aquaflex Ultrasound Gel Pad	04-02	085568300604000H8
Aquasonic 100 Ultrasound Transmission Gel	01-34	085568300601003GR
Aquasonic 100 Ultrasound Transmission Gel	01-50	085568300601003GR
Aquasonic 100 Ultrasound Transmission Gel	01-02	085568300601003GR
Aquasonic 100 Ultrasound Transmission Gel	01-08	085568300601003GR
Aquasonic 100 Ultrasound Transmission Gel	01-20	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-02	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-08	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-20	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-34	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-50	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-54	085568300601003GR
Polysonic Ultrasound Lotion	21-08	085568300620021HA
Polysonic Ultrasound Lotion	21-28	085568300620021HA
Polysonic Ultrasound Lotion (Polypac)	21-50	085568300620021HA
Polysonic Ultrasound Lotion with Aloe	20-08	085568300620021HA
Polysonic Ultrasound Lotion with Aloe	20-28	085568300620021HA
Polysonic Ultrasound Lotion with Aloe	20-50	085568300620021HA
Scan Ultrasound Gel	11-08	085568300601003GR
Scan Ultrasound Gel	11-28	085568300601003GR
Scan Ultrasound Gel (Scanpac)	11-28S	085568300601003GR