

MEDICAL DEVICES DIVISION

Granarolo dell'Emilia (BO), 2023/03/29

Stimata/Esteemed

MEDICA S.p.A

Via degli Artigiani ,7
41036 Medolla (MO)
Italia

Letter Reference: MDR 00048

Subject: Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

To whom it may concern,

This letter confirms that, Kiwa Cermet Italia, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MEDICA S.p.A
Via degli Artigiani ,7
41036 Medolla (MO)
Italia

SRN Number: IT-MF-000025691

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 20 March 2023, this letter also confirms that the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry (ref. MED 23010A rev 29 expiry date 17/03/2023)

Yours faithfully,



Spett.le

MEDICA S.p.A

Via degli Artigiani ,7
41036 Medolla (MO)
Italia

Riferimento lettera: MDR 00048

Oggetto: Conferma del ricevimento di una domanda formale e conclusione di un accordo scritto nell'ambito del Regolamento UE 2023/607 che modifica i Regolamenti (UE) 2017/745 e (UE) 2017/746 per quanto riguarda le disposizioni transitorie per taluni dispositivi medici e dispositivi medico- diagnostici in vitro.

A chi di interesse,

la presente lettera conferma che Kiwa Cermet Italia, Organismo Notificato (NB) designato ai sensi del Regolamento (UE) 2017/745 e identificato con il numero 0476 su NANDO, ha ricevuto domanda formale conformemente all'Allegato VII, punto 4.3, primo comma ed ha firmato un accordo scritto conformemente all'Allegato VII, punto 4.3, secondo comma del suddetto Regolamento con il seguente Fabbicante:

MEDICA S.p.A

Via degli Artigiani ,7
41036 Medolla (MO)
Italia

SRN: IT-MF-000025691

I dispositivi oggetto della domanda formale e dell'accordo scritto di cui sopra sono indicati alla fine della presente lettera.

In caso di dispositivi i cui certificati rilasciati ai sensi della Direttiva 93/42/CEE siano scaduti prima della pubblicazione del Regolamento UE 2023/607 del 20 Marzo 2023, la presente lettera conferma inoltre che il Fabbicante ha presentato domanda formale e firmato un accordo scritto entro la data di scadenza del certificato MDD (rif. doc.: MED 23010A rev 29 data di scadenza 17/03/2023).

In fede,

Kiwa Cermet Italia
Medical Devices Division
Division Manager

A handwritten signature in black ink, appearing to read "Alessio Fabbetti".

Devices covered by this letter/ Dispositivi oggetto della presente lettera:

Device name / Basic UDI-DI (under MDR application)	Device classification under MDR (as proposed by the manufacturer and verified at the pre-application stage)
SETS AND ACCESSORIES FOR ISOLATED PERFUSION OF A LIMB <u>BASIC UDI-DI:</u> 803377232BLD-ILP8Q	Class IIa
SETS AND ACCESSORIES FOR EXTRACORPOREAL BLOOD AND BLOOD PARTS MANAGEMENT <u>BASIC UDI-DI:</u> 803377232BLD-LBF7M	Class IIa
SETS AND ACCESSORIES FOR HEMODIALYSIS <u>BASIC UDI-DI:</u> 803377232BLD-HML8E	Class IIa
SETS AND ACCESSORIES FOR REMOVAL OF EXCESS CO ₂ <u>BASIC UDI-DI:</u> 803377232BLD-CO269	Class IIa
Sets for the treatment of Hypothermic Oxygenated Organ Perfusion <u>BASIC UDI-DI:</u> 803377232INF-ORPFF	Class IIa
Sets for the chemohyperthermic locoregional oncological treatments <u>BASIC UDI-DI:</u> 803377232INF-HTPEJ	Class IIa
Sets for the hemodialysis treatment <u>BASIC UDI-DI:</u> 803377232INF-DRLDG	Class IIa
Sets for hemofiltration <u>BASIC UDI-DI:</u> 803377232HMF-SETE6	Class IIb
Hemofiltration devices <u>BASIC UDI-DI:</u> 803377232HMFJ6	Class IIb
Hemoconcentration devices <u>BASIC UDI-DI:</u> 803377232HMCHY	Class IIb
Sets for hemoconcentration	Class IIb



<u>BASIC UDI-DI:</u> 803377232HMC-SETD5	
Catheters for oro-esophageal manometry	Class IIa
<u>BASIC UDI-DI:</u> 803377232CAT-G0103G6	
Catheters for gastro-intestinal manometry	Class IIa
<u>BASIC UDI-DI:</u> 803377232CAT-G0206GH	
Catheters for cyst- and urethronometry without balloon	Class IIa
<u>BASIC UDI-DI:</u> 803377232CAT-U0501MG	
Catheters for pressure-flow urinary study	Class IIa
<u>BASIC UDI-DI:</u> 803377232CAT-U0502MJ	
Catheters for urethral pressor without balloon	Class IIa
<u>BASIC UDI-DI:</u> 803377232CAT-U0503ML	
Catheters for measuring abdominal pressure	Class IIa
<u>BASIC UDI-DI:</u> 803377232CAT-U0504MN	
Catheters for Cavernosometry devices	Class IIa
<u>BASIC UDI-DI:</u> 803377232CAT-U0505MQ	
Urodynamic devices	Class IIa
<u>BASIC UDI-DI:</u> 803377232CAT-U0580N6	
Catheters for pelvic floor biofeedback exercise	Class IIa
<u>BASIC UDI-DI:</u> 803377232CAT-U0703MW	
Plasmafiltration devices	Class IIb
<u>BASIC UDI-DI:</u> 803377232PLSL5	
Sets for plasmafiltration	Class IIb
<u>BASIC UDI-DI:</u> 803377232PLS-SETNG	
Ultrafiltration devices for purification of dialysis fluid	Class IIa
<u>BASIC UDI-DI:</u> 803377232ULT-DIANB	
Ultrafiltration devices for purified water for reverse osmosis	Class IIa
<u>BASIC UDI-DI:</u> 803377232ULT-RWOSP	
Set of Ultrafiltration for purification of dialysis fluid	Class IIa



<u>BASIC UDI-DI:</u> 803377232ULT-DIA-SETPC	
Ultrafiltration devices for purified water for dental treatment units	Class IIa
<u>BASIC UDI-DI:</u> 803377232ULT-AMDNE	
Dialyzers with KUF < 18 ml/h/mmHg	Class IIb
<u>BASIC UDI-DI:</u> 803377232DIA-601Y8	
Dialyzers with KUF 18 - 35 ml/h/mmHg	Class IIb
<u>BASIC UDI-DI:</u> 803377232DIA-602YA	
Dialyzers with KUF > 35 ml/h/mmHg	Class IIb
<u>BASIC UDI-DI:</u> 803377232DIA-603YC	
Plasma fractionators	Class IIb
<u>BASIC UDI-DI:</u> 803377232FRAHZ	
Oxygenation devices for liver artery and portal vein perfusion	Class IIa
<u>BASIC UDI-DI:</u> 803377232OXY-SET-HEPAZ	
Oxygenation devices for kidney artery perfusion	Class IIa
<u>BASIC UDI-DI:</u> 803377232OXY-SET-KIDB4	
Systems for haemoperfusion and rheopheresis	Class IIb
<u>BASIC UDI-DI:</u> 803377232M3A-F2K	
Systems for hemoperfusion, therapeutic plasma exchange, rheopheresis and rheopheresis adsorption	Class IIb
<u>BASIC UDI-DI:</u> 803377232M3A-M2Z	
Systems for rheopheresis	Class IIb
<u>BASIC UDI-DI:</u> 803377232M3A-T3F	
System for hemoperfusion and endotoxins removal from blood	Class IIb
<u>BASIC UDI-DI:</u> 803377232M3EGJ	
Systems for hemoperfusion, therapeutic plasma exchange, rheopheresis and organ perfusion	Class IIb
<u>BASIC UDI-DI:</u> 803377232M76-P2H	
Systems for hemoperfusion	Class IIb



<u>BASIC UDI-DI:</u> 803377232M76-L29	
Systems for hemoperfusion, therapeutic plasma exchange, rheopheresis and rheopheresis adsorption	Class IIb
<u>BASIC UDI-DI:</u> 803377232M76-AZG	
Systems for organ perfusion	Class IIb
<u>BASIC UDI-DI:</u> 803377232M81FT	
BLUETOOTH TEMPERATURE SENSOR	Class IIb
<u>BASIC UDI-DI:</u> 803377232M81-BTSYE	
Measuring device for urology	Class Im
<u>BASIC UDI-DI:</u> 803377232MFZKJ	
Measuring device for urology	Class Im
<u>BASIC UDI-DI:</u> 803377232MP3J4	
Active diagnostic/rehabilitative medical devices for urodynamics	Class IIa
<u>BASIC UDI-DI:</u> 803377232MPD-PSB3	
Active diagnostic/rehabilitative medical devices for gastroenterology	Class IIa
<u>BASIC UDI-DI:</u> 803377232MPD-DS9X	
Systems for heart failure treatment	Class IIb
<u>BASIC UDI-DI:</u> 803377232M48FV	
Systems for hemoperfusion, decapneization and endotoxin removal	Class IIb
<u>BASIC UDI-DI:</u> 803377232M56FU	
Systems for haemofiltration	Class IIb
<u>BASIC UDI-DI:</u> 803377232M69G5	
Systems for haemofiltration	Class IIb
<u>BASIC UDI-DI:</u> 803377232M80FR	
Systems for oncology therapy	Class IIb



<u>BASIC UDI-DI:</u> 803377232MXPLL	
Warmer for haemofiltration, CRRT and hemoperfusion <u>BASIC UDI-DI:</u> 803377232MHTKC	Class IIb
leukocyte adsorber <u>BASIC UDI-DI:</u> 803377232ADSH2	Class IIa
Concentrator for plasma proteins and blood components <u>BASIC UDI-DI:</u> 803377232PRT-PRORP	Class IIa
Device for concentration and isolation of plasmatic proteins, exosomes, plasma vesicles, extracellular vesicles <u>BASIC UDI-DI:</u> 803377232PRT-EXOQJ	Class IIa



