MULTIMEDICAL s.r.l.
Via Guido Rossa 71, 46019,
Viadana (MN) - ITALIA

2024/04/30

Notified Body Confirmation Letter
Reference: <125333/24 REV.3 >

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance 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

This letter confirms that, ICIM SPA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0425 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:

MULTIMEDICAL s.r.l.
Via Guido Rossa 71, 46019,
Viadana (MN) - ITALIA
Numero SRN: <: IT-MF-000020128>

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,
ICIM SPA
Piazza Don Enrico Mapelli, 75
2099 Sesto Sam Giovanni MI
Identificazione su NANDO CE0425

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Lines and accessories for gravity infusion	Class <Is>	Gravity infusion sets and associated components, burettes, tubings, extension lines	Certificato G2S 014788 0025 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Lines and accessories for active devices	Class <IIa>	Infusion sets and associated components, burettes, tubings, extension lines	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Lines and accessories for infusion of contrast media	Class <IIa>	Infusion sets and associated components, burettes, tubings, extension lines	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Transfusion controllers	Class <IIa>	Transfusion sets	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Needles for infusion	Class <IIa>	Needles for infusion	Certificato G2 014788 0026 Rev.01

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			NB: n.0123 TUV SUD Product Service GmbH
Huber needles	Class <IIa>	Needles for infusion	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Kit toracentesi – paracentesi	Classe <IIa>	Kit for paracentesis and thoracentesis (needles, syringe, set and drainage bag)	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Controller for urological irrigation	Classe <Is>	Urology sets	Certificato G2S 014788 0025 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Arthroscopic irrigation controller	Classe <Is>	Athroscopy set	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Parenteral nutrition bags	Classe <Is>	Nutritrion bags	Certificato G2S 014788 0025 Rev.01
Tubings and surgical cannulae for surgical aspiration	Classe <IIa>	Tubings and surgical cannulae for surgical aspiration	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Elastomeric pumps	Classe <IIa>	Elastomeric infusion pumps	Certificato G1 014788 0503 Rev.00 NB: n.0123 TUV SUD Product Service GmbH

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/30		Initial issue

Remaining at your disposal for any clarification on the content of this offer, we take this opportunity to extend our best regards.

Dott. Edoardo Dossena
Product Sales Manager Product Certification, Inspections and Directives
ICIM S.p.A.

Ing. Flavia Lepore
Direttore Commerciale
ICIM S.p.A.

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	MULTIMEDICAL s.r.l.
Manufacturer address and contact details	Via Guido Rossa 71, Zona Ind.le Gerbolina- 46019, Viadana (MN) – ITALIA www.multimedical.it info@multimedical.it
Single Registration Number (SRN) (if available)	IT-MF-000020128

Notified body name (if applicable)	TUV SUD Product Service GmbH Zertifierstelle– Ridlerstrasse 65, 80339 Munchen - Germany
Notified body number (if applicable)	0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	G2S 014788 0025 Rev.01 G2 014788 0026 Rev.01 G1 014788 0503 Rev.00
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26
End date of extended validity/transition period	2028-12-31

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

MULTIMEDICAL S.r.l.
Via G. Rossa, 71 - Zona Ind. Gerbolina - 46019 VIADANA (MN) - **Tel. (0375) 785.882 - Telefax (0375) 785.885**
Cap. Soc. € 46.500,00 i.v. - C.C.I.A.A. Mantova n. 168271 - Reg. Soc. Trib. Impr. Mantova n. 3417/14834 - Cod. Fisc. e Part. IVA n. 01585920208 - P. IVA CEE IT01585920208
Internet : http://www.Multimedical.it - e-mail: info@Multimedical.it

Multimedical, as the manufacturer declares under its sole responsibility:

- for the above listed **Directive 93/42/EEC Certificates mentioned above** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **devices** in the attached schedule and Multimedical as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive 93/42/EEC Certificates** as listed above and in the attached schedule

- Directive 93/42/EEC Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards, expire *after* 20 March 2023,
- Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by Multimedical for the device(s) listed in the attached schedule or their substitutes and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for the manufacturer:

MULTIMEDICAL s.r.l.

Viadana, 2024/04/30

President, Legal Representative- GAVETTI ORESTE

info@multimedical.it

MULTIMEDICAL s.r.l.
Il Presidente
Gavetti Rag. Oreste

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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Internet : http://www.Multimedical.it - e-mail: info@Multimedical.it

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Gravity infusion sets and associated components, burettes	G2S 014788 0025 Rev.01	26/05/2024	TUV SUD Product Service GmbH n°0123	ICIM SPA n°0425	31/12/2028	
Tubings, extension lines	G2S 014788 0025 Rev.01	26/05/2024	TUV SUD Product Service GmbH n°0123	ICIM SPA n°0425	31/12/2028	
Nutrition bags	G2S 014788 0025 Rev.01	26/05/2024	TUV SUD Product Service GmbH n°0123	ICIM SPA n°0425	31/12/2028	
Urology sets	G2S 014788 0025 Rev.01	26/05/2024	TUV SUD Product Service GmbH n°0123	ICIM SPA n°0425	31/12/2028	
Transfusion sets,	G2 014788 0026 Rev.01	26/05/2024	TUV SUD Product Service GmbH n°0123	ICIM SPA n°0425	31/12/2028	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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Internet : http://www.Multimedical.it - e-mail: info@Multimedical.it

Infusion sets and associated components, burettes	G2 014788 0026 Rev.01	26/05/2024	TUV SUD Product Service GmbH n°0123	ICIM SPA n°0425	31/12/2028	
Tubings, extension lines,	G2 014788 0026 Rev.01	26/05/2024	TUV SUD Product Service GmbH n°0123	ICIM SPA n°0425	31/12/2028	
Needles for infusion	G2 014788 0026 Rev.01	26/05/2024	TUV SUD Product Service GmbH n°0123	ICIM SPA n°0425	31/12/2028	
Kit for paracentesis and thoracentesis (needles, syringes, set and drainage bag)	G2 014788 0026 Rev.01	26/05/2024	TUV SUD Product Service GmbH n°0123	ICIM SPA n°0425	31/12/2028	
Arthroscopy set	G2 014788 0026 Rev.01	26/05/2024	TUV SUD Product Service GmbH n°0123	ICIM SPA n°0425	31/12/2028	
Tubings and surgical cannulae for surgical aspiration	G2 014788 0026 Rev.01	26/05/2024	TUV SUD Product Service GmbH n°0123	ICIM SPA n°0425	31/12/2028	
Elastomeric infusion pumps	G1 014788 0503 Rev.00	26/05/2024	TUV SUD Product Service GmbH n°0123	ICIM SPA n°0425	31/12/2028	

Manufacturer's declaration revision History

Date	Action
2023/11/09	Initial issue
2024/04/30	Addition of devices "Tubings and surgical cannulae for surgical aspiration"

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 014788 0026 Rev. 01

Manufacturer:

Multimedical s.r.l.
Via G. Rossa 69, 71, 73
46019 Viadana (MN)
ITALY

Product Category(ies):

Transfusion sets, infusion sets and associated components, burettes, tubings, extension lines, needles for infusion, kit for paracentesis and thoracentesis (needles, syringe, set and drainage bag), arthroscopy set, tubings and surgical cannulae for surgical aspiration.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2 014788 0026 Rev. 01

Report No.: ITA1541104

Valid from: 2020-11-24
Valid until: 2024-05-26

Date, 2020-11-24

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany