ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 18 04 14788 025

Manufacturer:

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

Facility(ies):

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

Product Category(ies):

Gravity infusion sets and associated components: valves, connectors, adapters, filters, stopcocks, spikes, caps, manifolds, burette; tubing, extension lines, drainage bags, nutrition bags, urine bags, urology sets

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: ITA1033875

Valid from: 2018-05-12
Valid until: 2023-05-11

Date, 2018-04-17

Stefan Preiß

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

TÜV®

CE Sertifikatas

Gamybos kokybės užtikrinimo sistema

Direktyva 93/42/EEC Medicinos prietaisasm (MDD), Priedas V

(I klasės prietaisai steriliom sąlygom, sterilizuotos sistemos arba procedūrų paketai)

Nr. G2S 18 01 14788 025

Gamintojas: Multimedical s.r.l

Zona Ind. Gerbolina

Via G. Rossa 69,71,73

46019 Viadana (MN)

ITALIJA

Gamykla (-os): Multimedical s.r.l. Zona Ind. Gerbolina

Via G. Rossa 69,71,73, 46019 Viadana (MN), ITALIJA

Produktų kategorijos: Gravitacinių infuzijų rinkiniai ir susiję komponentai: vožtuvai, jungtys, adapteriai, filtrai, kraneliai, spike'ai, dangteliai, kolektoriai, biuretė; vamzdeliai, prailginimo linijos, drenažo maišeliai, mitybos maišeliai, šlapimo maišeliai, urologijos rinkiniai.

TUV SUD Product Services GmbH sertifikavimo įstaiga pareiškia, kad pirmiau minėtas gamintojas įdiegė gamybos kokybės užtikrinimo sistemą pagal MDD V priedą. Ši kokybės užtikrinimo sistema apima tuos gamybos aspektus, susijusius su atitinkamų prietaisų sterilių sąlygų užtikrinimu ir palaikymu. / prietaisų kategorijas ir atitinka šios direktyvos reikalavimus. Jai taikoma periodinė priežiūra. Taip pat žiūrėkite pastabas kitoje lapo pusėje.

Ataskaitos Nr.: ITA1033875

Galioja nuo: 2018-05-12

Galioja iki: 2023-05-11

Data, 2018-04-17

Parašas//

Stefan Preish

TUV SUD Product Services GmbH yra notifikuota įstaiga, kurios identifikavimo Nr. 0123

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.
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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

info@mu

MULTIMEDICAL s.r.l.
Il Presidente

[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"

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.

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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 ORE

info@multimedical.it

s.r.l.

[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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Schedule of Devices

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

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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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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"