Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

ISOMED (legal manufacturer)
Z.A.E Les Pointes - 230, rue des Grands Prés
60230 Chambly
France

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date June 07, 2024

Notified Body Confirmation Letter
Reference. : ISOMED_PLA0_HZ_2024-04-26 / 73083199

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 **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

ISOMED
Z.A.E Les Pointes - 230, rue des Grands Prés
60230 Chambly
France
SRN Number (if available): FR-MF-000018485

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 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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 March 20, 2023 for the relevant devices.

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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:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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

Malgorzata Blazniak
2024.06.07 08:30:46
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AUDIT_CERT_REVIEW
Certification body

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
INFU-KT Micro venous access port kit **INFU-KT Standard venous access port kit** **INFU-KT Low profile venous access port kit** **INFU-KT Optimized standard venous access port kit** **INFU-KT Optimized low profile venous access port kit**	Class III	INFU-KT titanium access port with catheter	MED 200026 NB#1014 MED 200028 NB#1014
Embolectomy balloon catheter single lumen **Embolectomy balloon catheter double lumen**	Class IIa	N/A	2204C04210402 NB#2803
Venous introducer with peel-away sheath **Venous introducer with standard sheath**	Class IIa	N/A	2204C04210402 NB#2803

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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-06-07	Revision 1	Initial issue

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod lisem 129/2, 171 02 Praha 8 - Troja

EC DESIGN-EXAMINATION CERTIFICATE

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll. (Annex II of Directive 93/42/EEC)

No.: MED 200026

The Electrotechnical Testing Institute, Notified Body No. 1014, performed the design examination of medical device

INFU-KT: implantable titanium access port with catheter - class III, see Enclosure

in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II clause 4 of Directive 93/42/EEC) at

manufacturer **ISOMed s.a.r.l**
ZAE Les Pointes 230, rue des Grands Prés, 60230 Chambly, France

and states that the design of medical device meets the provisions of Government Order No. 54/2015 Coll. (Directive 93/42/EEC)

The details of the medical device design examination are presented in the audit report No. MED000116-02/01a of: 25.05.2020.

The manufacturer must inform the notified body about any intention of substantial changes to the approved design of medical device which could affect the conformity with essential requirements in accordance with Annex 1 of Government Order No. 54/2015 Coll. (Annex I of Directive 93/42/EEC). In that case the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

Edition 1

The first issue of this certificate from 28.05.2020 with validity until 26.05.2024
The validity of this Certificate is limited until: 26.05.2024

29.07.2020

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja
Stamp

* C E R / M E D 2 0 0 0 2 6 *

Certificate history

Date	Status	Reason
28.05.2020	Issuance	Replacement of certificate No. MED 150084
29.07.2020	Change	Change of manufacturer's name

elektrotechnický zkušební ústav
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Podle letiště 129/2, 171 02 Praha 6 - Troja

INFU-KT: IMPLANTABLE TITANIUM ACCESS PORT WITH CATHETER

Reference	Designation
IAT 0823	Standard port for arterial access with catheter 0,8 x 2,3 x 600 mm
IVT 1020	Standard port for venous access with catheter 1,0 x 2,0 x 700 mm
IVT 1023	Standard port for venous access with catheter 1,0 x 2,3 x 700 mm
IVT 1026	Standard port for venous access with catheter 1,0 x 2,6 x 700 mm
IVT 1632	Standard port for venous access with catheter 1,6 x 3,2 x 700 mm
IPT 2648	Standard port for peritoneal access with catheter 2,6 x 4,8 x 500 mm
IAP 0823	Low profile port for arterial access with catheter 0,8 x 2,3 x 600 mm
IVP 1020	Low profile port for venous access with catheter 1,0 x 2,0 x 700 mm
IVP 1023	Low profile port for venous access with catheter 1,0 x 2,3 x 700 mm
IVP 1026	Low profile port for venous access with catheter 1,0 x 2,6 x 700 mm
IVP 1632	Low profile port for venous access with catheter 1,6 x 3,2 x 700 mm
IVM 0715	Micro port for venous access with catheter 0,7 x 1,5 x 700 mm
IVM 1020	Micro port for venous access with catheter 1,0 x 2,0 x 700 mm

End of list

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja