Signature Not Verified
Dokument podpisany przez Dariusz Mroziński
Data: 2024.06.07 13:39:22 CEST

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60141558 0001

Report No.: 26300445 002

Manufacturer:
TRANS-MED MEDICAL Sp. z o.o.
ul. Obroncow Poczty Gdanskiej 20P
42-400 Zawiercie
Polska

Products: (see attachment for products included)

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Notified Body

Effective Date: 2019-08-26

Date: 2019-08-26

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60141558 0001
Report No.: 26300445 002

Manufacturer: TRANS-MED MEDICAL Sp. z o.o.
ul. Obroncow Poczty Gdanskiej 20P
42-400 Zawiercie
Polska

Products included:

Non-sterile devices class IIa:
- medical zig-zag folded gauze (without X-ray thread)
- medical gauze square (without X-ray thread)
- gauze swabs (with or without X-ray thread)
- lap sponge (with or without X-ray thread)
- non-woven swabs (without X-ray thread)

Sterile devices class IIa:
- medical gauze square (without X-ray thread)
- gauze swabs (with or without X-ray thread)
- lap sponge (with or without X-ray thread)

Notified Body

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2019-08-26

TÜVRheinland®

Certyfikat EC

Dyrektywa 93/42/EEC Załącznik V
Zapewnienie Jakości Produkcji
dla Wyrobów Medycznych

Numer rejestracyjny: DD 60141558 0001

Numer raportu: 26300445 002

Wytwórca:
TRANS-MED MEDICAL Sp. z o.o.
ul. Obrońców Poczty Gdańskiej 20P
42-400 Zawiercie
Polska

Wyroby: (wyroby objęte według załącznika)

Data ważności: 2024-05-26

Jednostka Notyfikowana niniejszym deklaruje, że wymagania Załącznika V dyrektywy 93/42/EEC zostały spełnione dla wymienionych wyrobów. Wyżej wymieniony wytwórca ustanowił i stosuje system zapewnienia jakości, który podlega okresowym audytom nadzorującym na podstawie Załącznika V, sekcja 4 wyżej wymienionej dyrektywy. Dla wprowadzenia do obrotu wyrobów klasy IIb i klasy III objętych tym certyfikatem, wymagany jest certyfikat EC badania projektu według Załącznika III.

Ważny od: 2019-08-26

Data: 2019-08-26

Jednostka Notyfikowana

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH jest Jednostką Notyfikowaną według Dyrektywy 93/42/EEC dla wyrobów medycznych z numerem indentyfikacyjnym 0197.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Załącznik do Certyfikatu
Numer rejestracyjny: **DD 60141558 0001**
Numer raportu: **26300445 002**

Wytwórca: **TRANS-MED MEDICAL Sp. z o.o.**
ul. Obrońców Poczty Gdańskiej 20P
42-400 Zawiercie
Polska

Wyroby objęte:

Wyroby niesterylne, klasa IIa:
- gaza w składkach (bez nitki RTG)
- gaza opatrunkowa (bez nitki RTG)
- kompresy gazowe (z nitką lub bez nitki RTG)
- serwety z gazy (z nitką lub bez nitki RTG)
- kompresy włókninowe (bez nitki RTG)

Wyroby sterylne, klasa IIa:
- kompresy gazowe (bez nitki RTG)
- kompresy gazowe (z nitką lub bez nitki RTG)
- serwety z gazy (z nitką lub bez nitki RTG)

Jednostka Notyfikowana

Data: 2019-08-26

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Trans-Med Medical Sp. z o.o.
ul. Obrońców Poczty Gdańskiej 20P
42-400 Zawiercie
Poland

Contact

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

Date May 24, 2024

Notified Body Confirmation Letter
Reference. : TRANS_PLAQ0_HZ_2024_05_16 / 84975637

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:

Trans-Med Medical Sp. z o.o.
ul. Obrońców Poczty Gdańskiej 20P
42-400 Zawiercie
Poland

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.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

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
2024.05.24 17:13:13
+02'00'

Małgorzata Błaźniak
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:

No.	**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**
1.	Non-sterile Medical zig-zag folded gauze (without X-ray thread)	IIa	Non-sterile devices: Medical zig-zag folded gauze (without X-ray thread)	DD601415580001 0197
2.	Non-sterile Medical gauze square (without X-ray thread)	IIa	Non-sterile devices: Medical gauze square (without X-ray Thread)	DD601415580001 0197
3.	Non-sterile Gauze swabs (without X-ray thread)	IIa	Non-sterile devices: Gauze swabs (without X-ray thread)	DD601415580001 0197
4.	Non-sterile Gauze swabs (with X-ray thread)	IIa	Non-sterile devices: Gauze swabs (with X-ray thread)	DD601415580001 0197
5.	Non-sterile Lap sponge (without X-ray thread)	IIa	Non-sterile devices: Lap sponge (without X-ray thread)	DD601415580001 0197
6.	Non-sterile Lap sponge (with X-ray thread)	IIa	Non-sterile devices: Lap sponge (with X-ray thread)	DD601415580001 0197

7.	Non-sterile Non-woven swabs (without X-ray thread)	IIa	Non-sterile devices: Non-woven swabs (without X-ray thread)	DD601415580001 0197
8.	Sterile Medical gauze square (without X-ray thread)	IIa	Sterile devices: Medical gauze square (without X-ray thread)	DD601415580001 0197
9.	Sterile Medical gauze square (with X-ray thread)	IIa	Sterile devices: Medical gauze square (with X-ray thread)	DD601415580001 0197
10.	Sterile Gauze swabs (without X-ray thread)	IIa	Sterile devices: Gauze swabs (without X-ray thread)	DD601415580001 0197
11.	Sterile Gauze swabs (with X-ray thread)	IIa	Sterile devices: Gauze swabs (with X-ray thread)	DD601415580001 0197
12.	Sterile Lap sponge (without X-ray thread)	IIa	Sterile devices: Lap sponge (without X-ray thread)	DD601415580001 0197
13.	Sterile Lap sponge (with X-ray thread)	IIa	Sterile devices: Lap sponge (with X-ray thread)	DD601415580001 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
None			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/24	TRANS_CL607_2024_05_24	Initial issue