Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Taissis Concept Srl.,
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115100 Campulung, Romania

Contact

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

Date February 21, 2024

Notified Body Confirmation Letter
Reference. : 60366/2024

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:

Taissis Concept Srl.,
Ion Ticaloiu street no.17,
115100 Campulung, Romania
SRN Number: RO-MF-000001273

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.

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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

Dr.-Ing. Michael Fübi

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

Rafał Byczkowski
2024.02.21
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Rafał Byczkowski
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
Sterile polyurethane dressings with silicone, different sizes and shapes **Basic UDI-DI:** **5944729PANSPOLIURETAN83**	IIb	Sterile polyurethane with silicone dressing	HD 60148231 0001 #0197
Sterile polyurethane dressings with silicone - adhesive borders, different sizes and shapes **Basic UDI-DI:** **5944729PANSADEZIVPUCA**	IIb	Sterile polyurethane with silicone dressing	HD 60148231 0001 #0197
Sterile non-adhesive polyurethane dressings with hydrocolloid, different sizes **Basic UDI-DI:** **5944729PANSPOLIURETAN83**	IIb	Sterile polyurethane with hydrocolloid dressing	HD 60148231 0001 #0197
Sterile adhesive polyurethane dressings with hydrocolloid, different sizes and shapes	IIb	Sterile polyurethane with	HD 60148231 0001 #0197

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
Basic UDI-DI: 5944729PANSADEZIVPUCA		hydrocolloid dressing	
Sterile hydrocolloid dressings, different sizes Basic UDI-DI: 5944729PANSHIDROCOLOID3S	IIb	Sterile impregnates compresses with hydrocolloid	HD 60148231 0001 #0197
Sterile impregnated dressings for burns, different sizes Basic UDI-DI: 5944729COMPRESEARSURIVE	IIb	Sterile impregnated dressing and bandages with hydrogel	HD 60148231 0001 #0197
Sterile unidoses for burns, different volumes Basic UDI-DI: 5944729SPRAYURIUNIDOZEJB	IIa	Sterile hydrogel solution in sprays and unidoses unvelopes	HD 60148231 0001 #0197
Sterile sprays for burns, different volume Basic UDI-DI: 5944729SPRAYURIUNIDOZEJB	IIa	Sterile hydrogel solution in sprays and unidoses unvelopes	HD 60148231 0001 #0197
Sterile paraffin dressings, different sizes Basic UDI-DI: 5944729PANSIMPREGNJ9	IIb	Sterile paraffin dressing	HD 60148231 0001 #0197
Cold gel therapy compresses, tubes different sizes and volumes Basic UDI-DI: 5944729PRODGELRECEJU	IIa	Cold gel therapy	HD 60148231 0001 #0197
Isotonic saline BOV sprays, different, volumes Basic UDI-DI: 5944729SPRAYURINAZALETX	IIa	Cleaning/ irrigation solution for ENT	HD 60148231 0001 #0197
Isotonic seawater BOV sprays, different volumes Basic UDI-DI: 5944729SPRAYURINAZALETX	IIa	Cleaning/ irrigation solution for ENT	HD 60148231 0001 #0197
Hypertonic saline BOV sprays, different volumes Basic UDI-DI: 5944729SPRAYURINAZALETX	IIa	Cleaning/ irrigation solution for ENT	HD 60148231 0001 #0197
Hypertonic saline BOV sprays with hyaluronic acid and Menthol, different volumes	IIa	Cleaning/ irrigation solution for ENT	HD 60148231 0001 #0197

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
Basic UDI-DI: 5944729SPRAYURINAZALETX			
Hypertonic saline sprays with hyaluronic acid and Menthol, different volumes Basic UDI-DI: 5944729SPRAYURINAZALETX	IIa	Cleaning/ irrigation solution for ENT	HD 60148231 0001 #0197
Sterile single-use dialysis on-off kits, different contents Basic UDI-DI: 5944729SETURPANSSIASISTY2	Is	Sterile single-use dialysis on-off kits	HD 60148231 0001 #0197
Sterile single-use dialysis on-off kits, different contents Basic UDI-DI: 5944729SETURPANSSIASISTY2	IIa	Sterile single-use dialysis on-off kits	HD 60148231 0001 #0197
Sterile surgical kits and instruments for single use, different contents Basic UDI-DI: 5944729SETURIPROCEDURI6V	IIa	Sterile surgical kits and instruments for single use	HD 60148231 0001 #0197
Sterile surgical kits and instruments for single use, different contents Basic UDI-DI: 5944729SETURIPROCEDURI6V	Is	Sterile surgical kits and instruments for single use	HD 60148231 0001 #0197
Sterile single-use dressing kits, different contents Basic UDI-DI: 5944729SETURPANSSIASISTY2	IIa	Sterile single-use dressing kits, different contents	HD 60148231 0001 #0197
Sterile single-use dressing kits, different contents Basic UDI-DI: 5944729SETURPANSSIASISTY2	Is	Sterile single-use dressing kits	HD 60148231 0001 #0197
Sterile single-use Urinary kits, different contents Basic UDI-DI: 5944729SETURPANSSIASISTY2	IIa	Sterile single-use Urinary kits	HD 60148231 0001 #0197
Sterile single-use Urinary kits, different contents Basic UDI-DI: 5944729SETURPANSSIASISTY2	Is	Sterile single-use Urinary kits	HD 60148231 0001 #0197
Sterile single-use Enema kits, different contents	Is	Sterile single-use Enema kits	HD 60148231 0001

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
Basic UDI-DI: 5944729SETCLISMA5J			#0197
Sterile single-use obstetrics-gynecology kits, different contents Basic UDI-DI: 5944729SETURIGINECOX3	Is	Sterile single-use obstetrics-gynecology kits	HD 60148231 0001 #0197
Sterile single-use vaginal kits, different contents Basic UDI-DI: 5944729SETURIVAGINALEFY	Is	Sterile single-use obstetrics-gynecology kits	HD 60148231 0001 #0197
Sterile universal drapes kits, different contents Basic UDI-DI: 5944729SETURIPROCEDURI6V	Is	Sterile universal drapes kits	HD 60148231 0001 #0197
Sterile cardiology surgical drapes kits, different contents Basic UDI-DI: 5944729SETURIPROCEDURI6V	Is	Sterile cardiology surgical drapes kits	HD 60148231 0001 #0197
Sterile neurosurgery drapes kits, different contents Basic UDI-DI: 5944729SETURIPROCEDURI6V	Is	Sterile neurosurgery drapes kits	HD 60148231 0001 #0197
Sterile orthopaedics surgery drapes kits, different contents Basic UDI-DI: 5944729SETURIPROCEDURI6V	Is	Sterile orthopedics surgery drapes kits	HD 60148231 0001 #0197
Sterile urology surgical drapes kits, different contents Basic UDI-DI: 5944729SETURIPROCEDURI6V	Is	Sterile urology surgical drapes kits	HD 60148231 0001 #0197
Sterile obstetrics-gynecology surgical drapes kits, different contents Basic UDI-DI: 5944729SETURIPROCEDURI6V	Is	Sterile obstetrics-gynecology surgical drapes kits	HD 60148231 0001 #0197
Sterile gauze compresses, different sizes, plies Basic UDI-DI: 5944729COMPTIFONPLIATEBZ	Is	Sterile gauze nonwoven compresses	HD 60148231 0001 #0197
Sterile nonwoven balls, different sizes	IIa	Sterile gauze nonwoven compresses	HD 60148231 0001 #0197

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
Basic UDI-DI: 5944729TAMPNETESUTMF			
Sterile nonwoven folded compresses, different sizes and plies **Basic UDI-DI: 5944729COMPNETESUTPLIAT7C**	Is	Sterile gauze nonwoven compresses	HD 60148231 0001 #0197
Sterile gauze compresses, with Xray thread, different sizes, plies **Basic UDI-DI: 5944729COMPTIFONPLIATEBZ**	IIa	Sterile gauze nonwoven compresses	HD 60148231 0001 #0197
Sterile adhesive plasters, different sizes **Basic UDI-DI: 5944729PLASTNETESUTQR**	Is	Sterile plasters and strips	HD 60148231 0001 #0197
Sterile surgical gowns, standard, different sizes **Basic UDI-DI: 5944729HALATECHIRURGQQ**	Is	Sterile surgical gowns	HD 60148231 0001 #0197
Sterile surgical gowns, reinforced, different sizes **Basic UDI-DI: 5944729HALATERANFORSATEVE**	Is	Sterile surgical gowns	HD 60148231 0001 #0197
Sterile surgical drapes, different sizes and shapes **Basic UDI-DI: 5944729CAMPOPERATORIIDR**	Is	Sterile surgical drapes	HD 60148231 0001 #0197
Sterile surgical drapes, ophthalmology, different sizes **Basic UDI-DI: 5944729CAMPINCIZIEXX**	Is	Sterile surgical drapes	HD 60148231 0001 #0197
Sterile Mayo stand cover, different sizes **Basic UDI-DI: 5944729HUSEINSTRSIECHIPKP**	Is	Sterile surgical drapes	HD 60148231 0001 #0197
Sterile microscope protection cover, different sizes **Basic UDI-DI: 5944729HUSEINSTRSIECHIPKP**	Is	Sterile surgical drapes	HD 60148231 0001 #0197
Sterile camera protection cover, different sizes **Basic UDI-DI: 5944729HUSECAMERALS**	Is	Sterile surgical drapes	HD 60148231 0001 #0197

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-02-21	1	Initial issue