Institute for Testing and Certification
Notified Body NB 1023
trida Tomase Bati 299
Louky, 76302 Zlín
Czech Republic

In Zlín, on April 05, 2024

NB
Reference: 300/1166/2024

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, Institute for Testing and Certification, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1023 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:

STERIWUND spol. s r.o.
Lidická 43/886
763 01 Havířov – Šumbark
Czech Republic
SRN Number: CZ-MF-000036963

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Head office
Institut pro testovani a certifikaci, a.s.
trida Tomase Bati 299, Louky, 763 02 Zlin, Czech Republic

Office Svit area, building No.113
třída Tomase Bati 5264
760 01 Zlin, Czech Republic

Company Id.No: 47910381
VAT No: CZ47910381
Registered: KS Brno, RG.B/1002

☎ +420 572 779 922
✉ itc@itczlin.cz
🌐 www.itczlin.cz

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,

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

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
Kompres gázový 8vrst., sterilní Kompres gázový 12vrst., sterilní Kompres gázový 16vrst., sterilní Kompres gázový v krabičkách, sterilní Kompres 4vrst., sterilní Kompres prostřižený, 4vrst., sterilní Kompres vatový, sterilní Tampon stáčený Ba, sterilní Tampon prošívaný, předepraný s RTG tkanicí, sterilní	Class I sterile	N/A	EC Certificate – Production Quality Assurance No. 20 0001 QS/NB, rev. a issued by NB 1023

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Tampon prošívaný, nepředepraný s RTG tkanicí, sterilní			
Tampon stáčený s RTG tkanicí, sterilní			
Gáza vinutá – 4vrstvá, sterilní			
Gáza vinutá – 8vrstvá, sterilní			
Gázový přířez s buničitou vatou 4vrst., sterilní			
Obvaz hydrofilní pletený, sterilní			
Obvaz hotový s polštářkem č.2, č.3, č.4, sterilní			
Obvaz UNIVERSÁLNÍ, sterilní			
Obvaz elastický fixační, sterilní			
Kompres ušní špička-ryba skládaná, délka 6cm, sterilní			
Kompres nosní špička, délka 20cm, sterilní			
Tamponáda suchá 3vrst., sterilní			
Tamponáda suchá 4vrst., sterilní			
Tamponáda poševní průměr / váha sterilní			
Tamponáda suchá 4vrst., sterilní			
Tamponáda suchá gynekologická 4vrst., sterilní			
Rouška na instrumentační stolek, sterilní			
Rouška z netkané textilie, sterilní			
Rouška z netkané textilie pro chirurgické účely, sterilní			

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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
Rouška G s netkanou textilií, sterilní Rouška perforovaná z netkané textilie, sterilní Návlek na stolek, sterilní Návlek na mikroskop, sterilní Návlek na mikroskop s tkanicí, sterilní Návlek na C rameno, sterilní Návlek na C rameno SADA Návlek na kameru s gumičkou, sterilní Návlek na kameru, sterilní Návlek na zubní vrtačku, sterilní Návlek na ENDO kameru, sterilní Návlek na UZ sondu s tkanicí, sterilní Návlek na RTG štít 90x120 cm			
Mastný tyl s Vaselinum Album, sterilní	Class IIa	N/A	EC Certificate – Production Quality Assurance No. 15 0268 QS/NB, rev. b issued by NB 1023

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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
2024/04/05	300/1766/2024	Initial issue

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