schülke

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Date	22.05.2024

Prohlášení o prodloužení platnosti EC certifikátu pro zdravotnické prostředky

Schulke CZ, s.r.o. prohlašuje, že splnilo všechny požadavky dle článku 120 3c Nařízení 745/2017 pro uvádění zdravotnických prostředků na trh EU. Platnost stávajícícho certifikátu se prodlužuje do 31.12.2028.

V příloze přikládáme dopis o potvrzení splnění legislativních požadavků.

V případě vzniklých dotazů nás prosím kontaktujte.

S pozdravem,

.....

Ing. Andrea Lattenbergová
Marketing & Medical Affairs Director
schülke 1
Schulke CZ, s.r.o.
Lidická 445, 735 81 Bohumín
Czech Republic
IČ: 243 01 779, DIČ: CZ 243 01 779

Příloha č. 1: Confirmation letter , date 21.05.2024

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

In Zlín, on May 21, 2024

NB
Reference: 300/1319/2024

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:

Schulke CZ, s.r.o.
Lidická 445, Nový Bohumín, 735 81 Bohumín, Czechia
SRN Number: CZ-MF-000024068

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
trida 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

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
Medical device disinfectants		N/A	EC Certificate – Full Quality Assurance System No. 19 0229 QS/NB rev. a, issued by NB 1023
desam® effekt + desam® OX discleen® extra gigazyme® actifoam+	Class IIa		
chirosan® plus discleen® endo PAA	Class IIb		

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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
2024/05/21	300/1319/2024	Initial issue

Head office
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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*
- 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	Schulke CZ, s.r.o.
Manufacturer address and contact details.	Lidická 445, Nový Bohumín 735 14 Bohumín The Czech Republic
Single Registration Number (SRN) (if available)	CZ-MF-000024068

Notified body name (if applicable)	INSTITUTE FOR TESTING AND CERTIFICATION
Notified body number (if applicable)	1023
Directive Certificate number(s) to which this confirmation is made (if applicable)	19 0229 QS/NB rev. a
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	08.05.2024
End date of extended validity/transition period	31.12.2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached schedule and we 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 Certificate(s) as listed above or in the attached schedule
  - Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.
    - ☐ Expired/expires *after* 20 March 2023:
      - ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be 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 is in place.

- Device(s) as listed in the attached schedule
  - The devices continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices 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 and on behalf of the manufacturer:

Schulke CZ, s.r.o.

Bohumín, 22.05.2024

Print Name, Title: Ing. Jarmila Fafílková

Quality and Regulatory Affairs Manager

Contact Details: jarmila.fafilkova@schuelke.com

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Schedule of Devices

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

Identification of the device(s)[12] (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)
desam® effect +	19 0229 QS/NB rev. a	08.05. 2024	INSTITUTE FOR TESTING AND CERTIFICATION. NB 1023	INSTITUTE FOR TESTING AND CERTIFICATION,. NB 1023	31.12.2028	n/a
desam® OX	19 0229 QS/NB rev. a	08.05. 2024	INSTITUTE FOR TESTING AND CERTIFICATION, NB 1023	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	31.12.2028	n/a
gigazyme® actifoam+	19 0229 QS/NB rev. a	08.05. 2024	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	31.12.2028	n/a
discleen® extra	19 0229 QS/NB rev. a	08.05. 2024	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	31.12.2028	n/a
chirosan® plus	19 0229 QS/NB rev. a	08.05. 2024	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	31.12.2028	n/a
discleen® endo PAA	19 0229 QS/NB rev. a	08.05. 2024	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	INSTITUTE FOR TESTING AND CERTIFICATION NB 1023	31.12.2028	n/a

Schulke CZ, s.r.o.
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