

SERAG-WIESSNER GmbH & Co. KG
Zum Kugelfang 8-12
95119 Naila
Germany

Notified Body Confirmation Letter

Registration no.: D1453500011

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 mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0483 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:

**SERAG-WIESSNER GmbH & Co. KG
Zum Kugelfang 8-12
95119 Naila
Germany
SRN: DE-MF-000006422**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which a 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 a 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 20 March 2023 for the relevant devices.

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 Regulation (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)

Stuttgart, 2024-07-19



Head of Notified 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
KNOT PUSHHER MSD Ney	class IIa	N/A	D1453500002; NB#0483

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
SERALON, SUPRAMID, NYLON	class IIa	N/A	200038; NB#1014
SERANOX / SERANOX Ti	Class IIb excluding Class IIb implantable non-WET	N/A	200038; NB#1014
SERAFLEX	Class IIb excluding Class IIb implantable non-WET	N/A	200038; NB#1014
Polyester Tape	class IIa	N/A	200038; NB#1014
SERAPREN	class III	N/A	200029; NB#1014 200031; NB#1014
SERALENE	class III	N/A	200029; NB#1014 200032; NB#1014
SERAMON, SERAMON CHORDAE LOOP, KEYDENT, PLEDGET	class III	N/A	200029; NB#1014 200033; NB#1014
SERACOR, SULENE, TERYLENE	class III	N/A	200029; NB#1014 200030; NB#1014
SERASYNTH, SERASYNTH LOC	class III	N/A	200029; NB#1014 200035; NB#1014
SERAFAST	class III	N/A	200029; NB#1014 200036; NB#1014
SERAFIT, SERAPID	class III	N/A	200029; NB#1014 200034; NB#1014
SERAFIT PROTECT	class III	N/A	200029; NB#1014 190040; NB#1014
SERASYNTH MESH	class III	N/A	200029; NB#1014 200037; NB#1014

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
SERAGYN, SERAMESH, SERASIS, SERATOM, SERATEX (Textile Implants)	class III	N/A	200039; NB#1014
SILICONE LOOPS	class IIa	N/A	200040; NB#1014
Surgical Eye Needles SERAPRO RS	class IIa	N/A	200041; NB#1014
LAVANID 1, LAVANID 2	Class IIb excluding Class IIb implantable non-WET	N/A	200044; NB#1014
LAVANID Wound Gel, LAVANID Wound Gel V+	Class IIb excluding Class IIb implantable non-WET	N/A	200044; NB#1014
SERACIT	implantable non-WET	N/A	200043; NB#1014
Serag BSS	class IIa	N/A	200046; NB#1014
Aqua bidest irrigation solution	Class I devices placed on the market in sterile condition	N/A	200045; NB#1014
Column irrigation solutions (apheresis accessories) Elution solution NaCl 5 %, Glycine buffer pH 2.8, Sodium bicarbonate solution 1.4%, PBS, PBS + 0,01% NaN3. PBS-0,01% NaN3 blue	Class I devices placed on the market in sterile condition	N/A	200047; NB#1014
SERAPRO, SERASIS (re-usable surgical instruments)	Class I devices that qualify as re-usable surgical instruments	N/A	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-07-19	D1453500011	Initial