DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

Murrplastik Medizintechnik GmbH
Herr Paul Seidel
Gewerbering 11
08223 Falkenstein
Germany

DEKRA Certification GmbH
Handwerkstraße 15
D-70565 Stuttgart

Contact Hagji Gjelaj
Phone +49.40.23603-8770711.7861.3746
Fax +49.40.23603-840
Email hagji.gjelaj@dekra.com

Headquarters
Phone +49.711.7861-25662566
Fax +49.711.7861-2615

Date 2024-10-02

Subject: Notified Body Confirmation Letter

Our reference: 51163-CoL-02 Rev. 1

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 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Mr. Seidel

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 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:

Murrplastik Medizintechnik GmbH
Gewerbering 11
08223 Falkenstein
Deutschland

SRN Number (if available): DE-MF-000006855

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables 1 and 2 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 MDD.

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

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)

This confirmation letter with the registration no. 51163-CoL-01, Rev. 1, is invalid with immediate effect.

Validity of this confirmation letter:

For products included in table 1:

Until the end of applicable transition timelines specified in Article 120.3c of MDR (as amended by (EU) 2023/607)

On behalf of the Notified Body,

Karin-Marie Leicht

Digital unterschrieben von Karin-Marie Leicht
Datum: 2024-10-02 12:55:16+02:00

Karin Leicht

Enclosures:

Confirmation Letter Annex

Annex to Notified Body Confirmation Letter 51163-CoL-02 Rev. 1

Table 1

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	Agreement for Conformity Assessment
Neofact® Application Aid	Class IIa	N/A	51163-16-02, Rev. 0 NB 0124	51163-CA-00
Sterilset IIS (Endoskophalter für Soloassist IIS)	Class Is	N/A	51163-16-02, Rev. 0 NB 0124	51163-CA-00