DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

PATH MEDICAL GmbH
Mr. Florian Peters
Landsberger Straße 65
82110 Germering
Germany

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Date 2024-09-25

Subject: Notified Body Confirmation Letter

Our reference: 51260-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. Peters

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:

PATH MEDICAL GmbH
Mr. Florian Peters
Landsberger Straße 65
82110 Germering
Germany

SRN Number: DE-MF-000006935

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

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,

i.V.Markus Kopf

Director Medical Devices

Digital unterschrieben von Markus RAINER Kopf
Datum: 2024-09-25 18:26:03+02:00

Enclosures:

Confirmation Letter Annex

Annex to Notified Body Confirmation Letter 51260-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
0426022Sentiero-2aHJ	Class IIa	N/A	Certificate #51260-16-03 NB #0124
0426022ALGO7i-2aLU	Class IIa	N/A	Certificate #51260-16-03 NB #0124
0426022QScreen-2aDM	Class IIa	N/A	Certificate #51260-16-03 NB #0124
0426022TY-MU-2aNP	Class IIa	N/A	Certificate #51260-16-03 NB #0124
0426022Probes-2aTM	Class IIa	N/A	Certificate #51260-16-03 NB #0124
0426022Headphones-2a7R	Class IIa	N/A	Certificate #51260-16-03 NB #0124
0426022Earphones-2aQ9	Class IIa	N/A	Certificate #51260-16-03 NB #0124
0426022BoneConductor-2aTS	Class IIa	N/A	Certificate #51260-16-03 NB #0124
0426022ECC-2a5Z	Class IIa	N/A	Certificate #51260-16-03 NB #0124