DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

PATH medical GmbH
Herr Florian Peters
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Date 2023-08-23

Subject: Notified Body Confirmation Letter

Our reference: 51260-CoL-00, Rev.00

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, hereby confirms that a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer is still pending:

PATH medical GmbH
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Furthermore, DEKRA Certification GmbH confirms that an agreement between PATH medical GmbH and DEKRA Certification GmbH is in place about the surveillance of the products that are covered by the certificate mentioned in table 1 according to Regulation (EU) 2017/745 Article 120.

Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulation (EU) 2017/745 as regards the transitional provision for certain medical devices has been published on 20 March 2023 and came into force on the same day. This Regulation 2023/607 has amended MDR 2017/745 to now identify that under certain conditions certificates issued by Notified Bodies, as DEKRA Certification GmbH, in accordance with the MDD 93/42/EEC that were still valid on 26.05.2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the

certificate, see Table 1 under certain conditions. Additionally, should PATH medical intend to make use of the extension of the validity of the EC-certificates, involvement of DEKRA Certification GmbH for continued surveillance is required.

This Confirmation Letter identifies the products or product groups and EC certificates according to MDD 93/42/EEC (see Table 1) for which PATH medical GmbH intends to make use of the option for extension of the validity of the EC certificates (see Table 1).

This Confirmation Letter identifies its validity until the latest: **2024-05-25**.

If PATH Medical GmbH has intentions to make use of the option for extension of the validity of the EC certificates (see Table 1) as detailed in the amendment of the MDR 2017/745 by Regulation (EU) 2023/607:

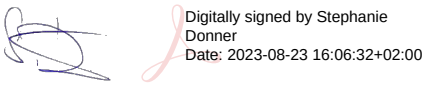
- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 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)

the following conditions have to be met:

- PATH MEDICAL GmbH or it's the Authorized Representative has to ensure that a formal application acc. to the MDR 2017/745 Section 4.3, first subparagraph of Annex VII for the conformity assessment will have been lodged with DEKRA Certification GmbH, latest by 26 May 2024. The application should be placed for the product(s) or groups of products intended to substitute those product(s).
- PATH MEDICAL GmbH or its Authorized Representative has to ensure that a written agreement in accordance with the MDR 2017/745 Section 4.3, second subparagraph of Annex VII will have been signed with DEKRA Certification GmbH, latest by 26 September 2024.

Should the MDR application not be lodged and the written agreement not to be signed acc. to the mentioned timelines, the EC certificates mentioned in the Table 1, cannot be considered valid after 26. September 2024.

On behalf of the Notified Body,



Stephanie Donner
2023-08-23

Table 1: Devices covered by this letter and for which the notified body DEKRA Certification GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Product or product group identification acc. to MDD -certificate	MDD Device classification	MDD Certificate and Certificate Annex No. with revision

Audiometer, + Diagnostic Device for otoacoustic emissions (OAE), + Diagnostic Device for auditory evoked potentials (AEP), + Tympanometer
• Senti, Model number:
  ○ SIH100097
• Senti (Type Desktop), Model number:
  ○ SID100419 (Vero)
  ○ SID100433 (Vero Flex)
• Sentiero, Model number: SOH100098
• Sentiero Advanced, Model number:
  ○ SOH100360
• Sentiero (Type Desktop), Model number:
  ○ SOD100497
	IIa	Certificate: No. 51260-16-03, dated 2020-12-11
		Annex revision 1, dated 2021-05-25
		NB 0124

Hearing Screener • AABR Newborn Hearing Screener ALGO7i, Model number: 101049 (A7i) • QSCREEN: OAE and ABR Hearing Screener, Model Number: 101199 (PM1610)	IIa	Certificate: No. 51260-16-03, dated 2020-12-11 Annex revision 1, dated 2021-05-25 NB 0124
Accessories for Audiometer, + Diagnostic Device for otoacoustic emissions (OAE), + Diagnostic Device for auditory evoked potentials (AEP), + Tympanometer • Ear Probe, Type: EP-TE, EP-DP, EP-LT, EP-VIP, EP-TY • Headphone, Insert Phone, Type: HP, IP • Bone Conductor, Type: BC • Ear Coupler Cable, Type: ECC, ATA (A7i)	IIa	Certificate: No. 51260-16-03, dated 2020-12-11 Annex revision 1, dated 2021-05-25 NB 0124
Tympanometer • nanoTymp, Model number: TU100948 (TY-MU)	IIa	Certificate: No. 51260-16-03, dated 2020-12-11 Annex revision 1, dated 2021-05-25 NB 0124