DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

Heinz Kurz GmbH
Frau Nicole Burr
Tübinger Straße 3
72144 Dusslingen
Germany

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Date 2024-11-28

Subject: Notified Body Confirmation Letter

Our reference: 50158-CoL-02 Rev. 2

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 Ms. Burr

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:

Heinz Kurz GmbH
Tübinger Straße 3
72144 Dusslingen
Deutschland

SRN Number (if available): DE-MF-000007959

Table 1 identifies the devices for which a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR has been concluded between Heinz Kurz GmbH and DEKRA Certification GmbH and for which DEKRA Certification GmbH 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 DEKRA Certification GmbH 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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)

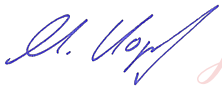
The confirmation letter 50158-CoL-02 Rev. 1 is invalid with immediate effect.

Validity of this confirmation letter:

For products included in table 1 and 2:

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,



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Datum: 2024-11-28 15:42:23+01:00

Markus Kopf

Enclosures:

Confirmation Letter Annex

Annex to Notified Body Confirmation Letter 50158-CoL-02 Rev. 02

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
Implant for Ventilation and Draining of the Middle Ear	Class IIb implantable	N/A	50158-16-06; 0124	50158-CA-00
Implants for Rhinoplasty	Class IIb implantable non- WET device	N/A	50158-16-06; 0124	50158-CA-00
Eyelid Implants	Class IIb implantable non- WET device	N/A	50158-16-06; 0124	50158-CA-00
Middle Ear Implants for Tympanoplasty	Class IIb implantable non- WET device	N/A	50158-16-06; 0124	50158-CA-00
Middle Ear Implants for Stapedioplasty	Class IIb implantable non- WET device	N/A	50158-16-06; 0124	50158-CA-00
AC-Sizer System	Class IIa	N/A	50158-17-07, 0124	50158-CA-00
Blades sterile single packed	Class I devices placed on the market in sterile condition	N/A	50158-17-07, 0124	50158-CA-00
Surgical instrument with measuring function	Class I devices with a measuring function	N/A	50158-17-07, 0124	50158-CA-00

Table 2

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
Malleus Handle Cavity Bending Pliers	Ir	n.a.	n.a.	50158-CA-00
Titanium Micro Closing Forceps	Ir	n.a.	n.a.	50158-CA-00
KURZ-Precise Cartilage Knife Set	Ir	n.a.	n.a.	50158-CA-00
Cutting Forceps	Ir	n.a.	n.a.	50158-CA-00
Micro Scissors	Ir	n.a.	n.a.	50158-CA-00
Cartilage Forceps Schimanski design	Ir	n.a.	n.a.	50158-CA-00
Cartilage Punch	Ir	n.a.	n.a.	50158-CA-00
SteadyCrimp Forceps	Ir	n.a.	n.a.	50158-CA-00
Soft CliP Hook	Ir	n.a.	n.a.	50158-CA-00
Sizer Omega Connector	IIa	n.a.	n.a.	50158-CA-00
Sizer Breathe Implant àWengen	IIa	n.a.	n.a.	50158-CA-00