DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

RECK-Technik GmbH & Co. KG

Reckstraße 1-5
88422 Betzenweiler

Germany

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Date 2024-10-02

Subject: Notified Body Confirmation Letter

Our reference: 50293-CoL-01 Rev.0

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. or Mr.

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:

RECK-Technik GmbH & Co. KG

Reckstraße 1-5
88422 Betzenweiler

Germany

SRN Number: DE-MF-000005730

The devices covered by the formal application and the written agreement mentioned above are identified in Table 1 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the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)
- 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: 2024-10-23 17:35:26+02:00

Markus Kopf
2024-10-02

Enclosures:

Confirmation Letter Annex

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
MOTOmed loop edition 4260193710027P Variants: MOTOmed loop.l MOTOmed loop.a MOTOmed loop.la MOTOmed loop.la prof MOTOmed loop p.l MOTOmed loop p.la MOTOmed loop kidz.l MOTOmed loop kidz.a MOTOmed loop kidz.la MOTOmed loop light.l MOTOmed loop light.a MOTOmed loop light.la	Class IIa Annex VIII Rule 9	MOTOmed loop Variants: MOTOmed loop.l MOTOmed loop.a MOTOmed loop.la MOTOmed loop.la prof MOTOmed loop p.l MOTOmed loop p.la MOTOmed loop kidz.l MOTOmed loop kidz.a MOTOmed loop kidz.la MOTOmed loop light.l MOTOmed loop light.a MOTOmed loop light.la (Transfer from MDD to MDR)	EC Certificate No. 50293-16-05 Annex to the EC Certificate No. 50293-16-05 Rev1, 2020-06-02 Device: “MOTOmed loop” NB: DEKRA Certification GmbH Stuttgart, 0124
MOTOmed layson edition 4260193710037R Variants: MOTOmed layson.l parallel chassis MOTOmed layson.la parallel chassis MOTOmed layson.l expandable chassis MOTOmed layson.l dia expandable chassis MOTOmed layson.la expandable chassis MOTOmed layson.la prof MOTOmed layson.kidz.l parallel chassis MOTOmed layson.kidz.la parallel chassis MOTOmed layson.kidz.l expandable chassis MOTOmed layson.kidz.la expandable chassis	Class IIa Annex VIII Rule 9	MOTOmed layson edition Variants: MOTOmed layson.la parallel chassis MOTOmed layson.l expandable chassis MOTOmed layson.l dia expandable chassis MOTOmed layson.la expandable chassis MOTOmed layson.la prof MOTOmed layson.kidz.l parallel chassis MOTOmed layson.kidz.la parallel chassis MOTOmed layson.kidz.l expandable chassis MOTOmed layson.kidz.la expandable chassis (Transfer from MDD to MDR)	EC Certificate No. 50293-16-05 Annex to the EC Certificate No. 50293-16-05 Rev1, 2020-06-02 Device: “MOTOmed layson edition” NB: DEKRA Certification GmbH Stuttgart, 0124
MOTOmed muvi 4260193710057V	Class IIa Annex VIII Rule 9	MOTOmed muvi (Transfer from MDD to MDR)	EC Certificate No. 50293-16-05 Annex to the EC Certificate No. 50293-16-05 Rev1, 2020-06-02 Device: “MOTOmed muvi” NB: DEKRA Certification GmbH Stuttgart, 0124

MOTOmed gracile edition 4260193710588J Variants: MOTOmed gracile.l MOTOmed gracile.la	Class IIa Annex VIII Rule 9	MOTOmed gracile12 *Will be replaced by „MOTOmed gracile edition“* End date of extended validity / transition period according to Regulation (EU) 2023/607: 2028-12-31	EC Certificate No. 50293-16-05 Annex to the EC Certificate No. 50293-16-05 Rev1, 2020-06-02 Device: “MOTOmed gracile12” NB: DEKRA Certification GmbH Stuttgart, NB 0124