DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

PRISMAN GmbH
Frau Dr. Kathrin Benzing
Otto-Hahn-Ring 6 -18
64653 Lorsch
Deutschland

DEKRA Certification GmbH
Handwerkstraße 15
D-70565 Stuttgart

Contact Yevgeniya Siller
Phone -
Fax -
Email yevgeniya.siller@dekra.com

Headquarters
Phone +49.711.7861-2566
Fax +49.711.7861-2615

Date 2024-03-27

Subject: Notified Body Confirmation Letter

Our reference: 50681-CoL-00, 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

Dear Ms. Dr. Benzing

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

(1) 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 for the listed devices in the Tabel 1 with the following manufacturer:

PRISMAN GmbH
Otto-Hahn-Ring 6 -18
64653 Lorsch
Deutschland

(2) 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 for the listed devices in the Tabel 2 with the following manufacturer is still pending:

PRISMAN GmbH
Otto-Hahn-Ring 6 -18
64653 Lorsch
Deutschland

Tables 1 and 2 identify the devices for which the NB (0124) is also responsible for appropriate surveillance of the corresponding devices under

(1) the applicable Directive 93/42/EEC (MDD), Annex II excl. section 4;

(2) the applicable Directive 93/42/EEC (MDD), Annex V.

The table 3 identifies the devices for which an MDR application has been received but the NB (0124) has not responsible for appropriate surveillance of the corresponding devices under the MDD due to their low classification (class I).

In the case of devices covered by certificates issued under MDD that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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 the Tabel 1, 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)

Furthermore, DEKRA Certification GmbH confirms that an agreement between PRISMAN GmbH and DEKRA Certification GmbH is in place about the surveillance of the products that are covered by the certificate(s) mentioned in the Tabels 1 and 2 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 EC certificates issued by Notified Bodies, as DEKRA Certification GmbH (0124), in accordance with the MDD 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 (2024-05-26). Additionally, should the PRISMAN GmbH 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 devices and EC certificates according to MDD for which PRISMAN GmbH intends to make use of the option for extension of the validity of the EC certificates (see Tables 1 and 3).

If PRISMAN GmbH has intentions to make use of the option for extension of the above mentioned validity for the devices covered mentioned in the Table 1 & 3 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)

On behalf of the Notified Body,

Digitally signed by Stephanie Donner
Date: 2024-03-27 08:18:35+01:00

Stephanie Donner
2024-03-27

Enclosures:

Confirmation Letter Annex

Annex to Notified Body Confirmation Letter 50681-CoL-00, Rev. 0

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 Annex MDD:

Product or product group identification acc. to MDD -certificate	MDD Device classification	MDD Certificate and Certificate Annex No. with revision
Instrumentendesinfektion BASIS Konz., ID 200 conc. (inkl. ZYME)	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion FINISH, ID 710	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion POW(D)ER PLUS Konz., IPD 400 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion POW(D)ER HIGH Konz., IDP 700 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumenten Desinfektionsreiniger SOLIDSEPT Konz., IC 270 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion PREMIUM PLUS Konz., ID 470	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion PREMIUM HIGH Konz., ID 770 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion VIREX BASIC Konz., ID 200 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion VIREX HIGH Konz., ID700 coc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Bohrerbad PLUS, DB 400	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Bohrerbad HIGH, DB 700	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Bohrerbad VIREX, DB 700	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Flächendesinfektion VIREX FORTE SD 710 inkl. Desinfektionstücher	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28

Flächendesinfektion VIREX BASIC Konz., SD 200 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Flächendesinfektion VIREX PLUS Konz., SD 400 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Flächendesinfektion VIREX HIGH Konz., SD 700 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Sprüh- Wischdesinfektion BIO, RSD 410 inkl. Desinfektionstücher	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Sprüh- und Wischdesinfektion MAX, RSD 500 inklusive Desinfektionstücher	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Sprüh- und Wischdesinfektion MAX, RSD 600 inklusive Desinfektionstüchern	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Sprüh- und Wischdesinfektion MED, RSD 700 inklusive Desinfektionstücher	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Absauganlagendesinfek-tion Konz., SS 400 conc.	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion Konz., SD 300 conc.	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion PROTECT Konz., SD 420	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion RAPID FOAM PLUS, RFD 440 inkl. Desinfektionstücher	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion RAPID FOAM HIGH, RFD 740 inklusive Desinfektionstücher	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Abformdesinfektion PLUS, IM 400	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Abformdesinfektion, IM 200	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02

Mundspülbeckendesinfek-tion SPITOON, SP 400	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Mundspülbeckendesinfek-tion NANO, SPN 700	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Sprüh-Wischdesinfektion, RSD 400 inklusive Desinfektionstücher	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Ätzgel	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Primer Silanisierungsliquid SILANO	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion BASIC Konz., SD 200 conc.	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02

Annex to Notified Body Confirmation Letter 50681-CoL-00, Rev. 0

Table 2: 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 Annex MDD until 2024-05-26:

Product or product group identification acc. to MDD -certificate	MDD Device classification	MDD Certificate and Certificate Annex No. with revision	MDR Application: "Yes"/"No" If "Yes", MDR device classification (as proposed by the manufacturer and verified at the pre-application stage)
Instrumentendesinfektion Konz., ID 300 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28	☐ Yes ☒ No
Instrumentendesinfektion PLUS Konz., ID 400 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28	☐ Yes ☒ No
Bohrerbad, DB 200	IIb	EU-certificate acc. to Anx. II excl. section 4 MDD No.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28	☐ Yes ☒ No
Flächendesinfektion PREMIUM Konz., SD 240 conc.	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02	☐ Yes ☒ No
Abformdesinfektion, IM 250	IIa	EU-certificate acc. to Anx. V MDD No.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02	☐ Yes ☒ No

Annex to Notified Body Confirmation Letter 50681-CoL-00, Rev. 0

Table 3: Devices covered by this letter and for which the NB (0124) is NOT responsible but a subject for appropriate surveillance of the corresponding devices under the certification scope of the EN ISO 13485 certificate:

Product or product group identification acc. to MDD	MDD Device classification	If the MDR device is a substitute device, identification of the corresponding MDD device	MDR Application: "Yes"/"No" If "Yes", MDR device classification (as proposed by the manufacturer and verified at the pre-application stage)
Prophylaxepulver PROPHY FRESH, PROPHY TOP, PROPHY SOFT, PROPHY PERIO PLUS, PROPHY SOFT PERIO	I No Notified Body was required	Prophylaxepulver PROPHY FRESH, PROPHY TOP, PROPHY SOFT, PROPHY PERIO PLUS, PROPHY SOFT PERIO	☒ Yes ☐ Class III ☐ Class IIb ☒ Class IIa ☐ Class Is ☐ Class Im ☐ Class Ir MDR Application ID: Change Notification ÄM-50681-CN24-01 dd. 2024-03-06 to A22051578 ☐ No