DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

PRISMAN GmbH
Frau Dr. Simone Neef-Sartorius
Otto-Hahn-Ring 6 -18
64653 Lorsch
Germany

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Date 2024-11-19

Subject: Notified Body Confirmation Letter
Our reference: 50681-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. Neef-Sartorius,
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 from the following manufacturer for the devices listed in the annex:

PRISMAN GmbHPRISMAN GmbH
Otto-Hahn-Ring 6 -18
64653 Lorsch
Deutschland
SRN Number: DE-MF-000009900

Table 1 identifies the devices for which a 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 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

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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 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
i.V. Markus Kopf
Director Medical Devices

Enclosures:
Confirmation Letter Annex

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Annex to Notified Body Confirmation Letter 50681-CoL-02 Rev.2

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
Instrumentendesinfektion POW(D)ER PLUS Konz., IDP 400 conc./ Instrument Disinfection POW(D)ER PLUS conc, IDP 400 conc.	IIb	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Flächendesinfektion VIREX HIGH Konz., SD 700 conc./Surface Disinfection VIREX HIGH Konz., SD 700 conc.	IIb	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Instrumentendesinfektionsmittel PREMIUM HIGH Konz., ID 770 conc./Instrument Disinfection PREMIUM HIGH conc, ID 770 conc.	IIb	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Flächendesinfektion VIREX FORTE, SD 710 inklusive Desinfektionstüchern/Surface Disinfection VIREX FORTE, SD 710 including Disinfection Wipes	IIb	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Sprüh- und Wischdesinfektion, RSD 400 inklusive Desinfektionstücher/Rapid Surface Disinfection, RSD 400 including Disinfection Wipes	IIa	n.a.	MDD Annex V: 50681-17-05 NB0124
Instrumentendesinfektion BASIS Konz., ID 200 conc. (inkl. Zyme)/Instrument Disinfection BASIS conc., ID 200 conc. (incl. Zyme)	IIa	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Instrumentendesinfektion FINISH, ID 710	IIb	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124

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Instrumenten Desinfektionsreiniger SOLIDSEPT Konz., IC 270 conc./ Instrument Disinfection Cleaner SOLIDSEPT conc., IC 270 conc.	IIb	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Instrumentendesinfektion PREMIUM PLUS Konz., ID 470 conc./Instrument Disinfection PREMIUM PLUS conc., ID 470 conc.	IIb	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Flächendesinfektion VIREX BASIS Konz., SD 200 conc./ Surface Disinfection VIREX BASIC conc., SD 200 conc.	IIa	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Instrumentendesinfektion POW(D)ER HIGH Konz., IDP 700 conc./ /Instrument Disinfection POW(D)ER HIGH conc., IDP 700 conc.	IIb	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Bohrerbad PLUS, DB 400/ Drill Bath PLUS, DB 400	IIa	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Bohrerbad HIGH, DB 700/Drill Bath HIGH, DB 700	IIb	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Bohrerbad VIREX, DB 700/Drill Bath VIREX, DB 700	IIb	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Flächendesinfektion VIREX PLUS Konz., SD 400 conc./ Surface Disinfection VIREX PLUS conc., SD 400 conc.	IIa	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Sprüh- und Wischdesinfektion BIO, RSD 410 inklusive Desinfektionstüchern/Rapid Surface Disinfection, RSD 410 including Disinfection Wipes	IIa	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Sprüh- und Wischdesinfektion MAX, RSD 500 inklusive Desinfektionstücher/Rapid Surface Disinfection MAX, RSD 500 including Disinfection Wipes	IIa	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Sprüh- und Wischdesinfektion MAX, RSD 600 inklusive	IIa	n.a.	MDD Annex II excl. section 4: 50681-16-04

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Desinfektionstüchern/Rapid Surface Disinfection MAX, RSD 600 including Disinfection Wipes			NB0124
Sprüh- und Wischdesinfektion MED, RSD 700 inklusive Desinfektionstücher/Rapid Surface Disinfection MED, RSD 700 including Disinfection Wipes	IIa	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Absauganlagendesinfektion Konz., SS 400 conc./ Suction System Disinfection conc., SS 400 conc.	IIa	n.a.	MDD Annex V: 50681-17-05 NB0124
Flächendesinfektion Konz., SD 300 conc./Surface Disinfection conc., SD 300 conc.	IIa	n.a.	MDD Annex V: 50681-17-05 NB0124
Flächendesinfektion PROTECT Konz., SD 420 conc./Surface Disinfection PROTECT conc., SD 420 conc.	IIa	n.a.	MDD Annex V: 50681-17-05 NB0124
Flächendesinfektion RAPID FOAM PLUS, RFD 440 inklusive Desinfektionstüchern/Surface Disinfection RAPID FOAM PLUS, RFD 440 including Disinfection Wipes	IIa	n.a.	MDD Annex V: 50681-17-05 NB0124
Flächendesinfektion RAPID FOAM HIGH, RFD 740 inklusive Desinfektionstücher/ Surface Disinfection RAPID FOAM HIGH, RFD 740 including Disinfection Wipes	IIa	n.a.	MDD Annex V: 50681-17-05 NB0124
Abformdesinfektion PLUS, IM 400/ Impression Disinfection PLUS, IM 400	IIb	n.a.	MDD Annex V: 50681-17-05 NB0124
Abformdesinfektion, IM 200/Impression Disinfection, IM 200	IIb	n.a.	MDD Annex V: 50681-17-05 NB0124
Mundspülbeckendesinfektion SPITOON, SP 400	IIa	n.a.	MDD Annex V: 50681-17-05 NB0124
Mundspülbeckendesinfektion NANO, SPN 700/Spittoon Disinfection NANO, SPN 700	IIa	n.a.	MDD Annex V: 50681-17-05 NB0124
Ätzgel/Etching Gel	IIa	n.a.	MDD Annex V: 50681-17-05 NB0124
Silanisierungsliquid SILANO/ Silanization liquid SILANO	IIa	n.a.	MDD Annex V: 50681-17-05 NB0124

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Flächendesinfektion BASIS Konz., SD 200 conc./ Surface Disinfection BASIS conc., SD 200 conc.	IIa	n.a.	MDD Annex V: 50681-17-05 NB0124
Instrumentendesinfektion VIREX HIGH Konz., ID 700 conc./Instrument Disinfection VIREX HIGH conc., ID 700 conc.	IIb	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124
Instrumentendesinfektion VIREX BASIC Konz., ID 200 conc. / Instrument Disinfection VIREX BASIC conc., ID 200 conc.	IIa	n.a.	MDD Annex II excl. section 4: 50681-16-04 NB0124

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
Prophylaxepulver/ Prophylaxis Powder PROPHY TOP PROPHY SOFT PROPHY PERIO PLUS PROPHY SOFT PERIO	IIa	n.a.	N/A - Device did not require a Notified Body certificate under Directives

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