

TÜV Rheinland LGA Products GmbH • 51105 Köln

Wöhlk Contactlinsen GmbH
Bürgermeister-Schade-Straße 12-16
24232 Schönkirchen
Germany

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date June 03, 2024

Notified Body Confirmation Letter

Reference: WOEHL_PLA0_HZ_2024-05-31

To whom it may concern,

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

Wöhlk Contactlinsen GmbH
Bürgermeister-Schade-Straße 12-16
24232 Schönkirchen
Germany
SRN Number (if available): DE-MF-000022424

The devices covered by the formal application and the written agreement mentioned above are identified in the tables 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 under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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 March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Thomas Weigand, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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



 Digital unterschrieben
 von Karsten Kluge
 Datum: 2024.06.03
 16:02:05 +02'00'
 i.V. Dr. Karsten Kluge
 Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

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
CONTACT individual BIO	IIa	N/A	HD 1566826-1 NB 0197
CONTACT individual BIO TD	IIa	N/A	HD 1566826-1 NB 0197
CONTACT individual BIO TDS	IIa	N/A	HD 1566826-1 NB 0197
CONTACT individual BIO TP	IIa	N/A	HD 1566826-1 NB 0197
CONTACT individual multi BIO	IIa	N/A	HD 1566826-1 NB 0197
CONTACT individual multi BIO TD	IIa	N/A	HD 1566826-1 NB 0197
CONTACT individual multi BIO TDS	IIa	N/A	HD 1566826-1 NB 0197
CONTACT individual multi BIO TP	IIa	N/A	HD 1566826-1 NB 0197
CONTACT individual multi SH	IIa	N/A	HD 1566826-1 NB 0197
CONTACT individual multi SH TD	IIa	N/A	HD 1566826-1 NB 0197
CONTACT individual multi SH TDS	IIa	N/A	HD 1566826-1 NB 0197
CONTACT individual multi SH TP	IIa	N/A	HD 1566826-1 NB 0197

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
CONTACT individual SH	Ila	N/A	HD 1566826-1 NB 0197
CONTACT individual SH TD	Ila	N/A	HD 1566826-1 NB 0197
CONTACT individual SH TDS	Ila	N/A	HD 1566826-1 NB 0197
CONTACT individual SH TP	Ila	N/A	HD 1566826-1 NB 0197
CONTACT life spheric	Ila	N/A	HD 1566826-1 NB 0197
CONTACT life toric	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI AS 2 BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI AS 2 BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI AS 2 RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI AS 2 VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_as	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_as 2	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_as 2 BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_as 2 BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_as 2 RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_as 2 VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_as BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_as BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_as RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_as VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo as	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo as BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo as BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo as RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo as VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo as2	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo as2 BTK	Ila	N/A	HD 1566826-1 NB 0197

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
Diagnoselinse EGO_bifo as2 RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo as2 VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo mas	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo mas RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo mas VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo s 2k	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo s 2k BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo s 2k BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo s 2k RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo s 2k VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo s 3k	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo s 3k BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo s 3k BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo s 3k RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_bifo s 3k VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_ke	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_ke BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_ke BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_ke RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_ke VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_mas	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_mas BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_mas BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_mas RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_mas VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi as	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi as 2	Ila	N/A	HD 1566826-1 NB 0197

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
Diagnoselinse EGO_multi as 2 BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi as 2 BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi as 2 RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi as 2 VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi as BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi as BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi as RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi as VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi FEN	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi FEN BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi FEN RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi FEN VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi mas	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi mas BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi mas BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi mas RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi mas VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi s 2k	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi s 2k BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi s 2k BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi s 2k RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi s 2k VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi s 3k	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi s 3k BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi s 3k BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi s 3k RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_multi s 3k VPT	Ila	N/A	HD 1566826-1 NB 0197

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
Diagnoselinse EGO_s 2k	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_s 2k BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_s 2k BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_s 2k RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_s 2k VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_s 3k	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_s 3k BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_s 3k BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_s 3k RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse EGO_s 3k VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk AS	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk AS 2	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk AS 2 BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk AS 2 BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk AS 2 RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk AS 2 VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk AS BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk AS BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk AS RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk AS VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO AS	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO AS 2	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO AS 2 BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO AS 2 BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO AS 2 RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO AS 2VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO AS BT	Ila	N/A	HD 1566826-1 NB 0197

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
Diagnoselinse wöhlk BIFO AS BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO AS RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO AS VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk BIFO S 2K	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk BIFO S 2K BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk BIFO S 2K BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk BIFO S 2K RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk BIFO S 2K VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk bifo S 3K	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk bifo S 3K BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk bifo S 3K BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk bifo S 3K RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk bifo S 3K VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk KE	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk KE BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk KE BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk KE RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk KE VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI AS	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI AS 2	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI AS BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI AS BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI AS RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI AS VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI FEN	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI FEN BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI FEN RT	Ila	N/A	HD 1566826-1 NB 0197

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
Diagnoselinse wöhlk MULTI FEN VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI S 2K	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI S 2K BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI S 2K BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI S 2K RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI S 2K VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI S 3K	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI S 3K BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI S 3K BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI S 3K RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI S 3K VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk S 2K	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk S 2K BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk S 2K BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk S 2K RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk S 2K VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk S 3K	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk S 3K BT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk S 3K BTK	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk S 3K RT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse Wöhlk S 3K VPT	Ila	N/A	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO PAUL MAS	Ila	Diagnoselinse wöhlk BIFO MAS	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO PAUL MAS BT	Ila	Diagnoselinse wöhlk BIFO MAS BT	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO PAUL MAS BTK	Ila	Diagnoselinse wöhlk BIFO MAS BTK	HD 1566826-1 NB 0197
Diagnoselinse wöhlk BIFO PAUL MAS RT	Ila	Diagnoselinse wöhlk BIFO MAS RT	HD 1566826-1 NB 0197

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
Diagnoselinse wöhlk BIFO PAUL MAS VPT	Ila	Diagnoselinse wöhlk BIFO MAS VPT	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI PAUL MAS	Ila	Diagnoselinse wöhlk MULTI MAS	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI PAUL MAS BT	Ila	Diagnoselinse wöhlk MULTI MAS BT	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI PAUL MAS BTK	Ila	Diagnoselinse wöhlk MULTI MAS BTK	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI PAUL MAS RT	Ila	Diagnoselinse wöhlk MULTI MAS RT	HD 1566826-1 NB 0197
Diagnoselinse wöhlk MULTI PAUL MAS VPT	Ila	Diagnoselinse wöhlk MULTI MAS VPT	HD 1566826-1 NB 0197
Diagnoselinse wöhlk PAUL MAS BT	Ila	Diagnoselinse wöhlk MAS BT	HD 1566826-1 NB 0197
Diagnoselinse wöhlk PAUL MAS BTK	Ila	Diagnoselinse wöhlk MAS BTK	HD 1566826-1 NB 0197
Diagnoselinse wöhlk PAUL MAS RT	Ila	Diagnoselinse wöhlk MAS RT	HD 1566826-1 NB 0197
Diagnoselinse wöhlk PAUL MAS VPT	Ila	Diagnoselinse wöhlk MAS VPT	HD 1566826-1 NB 0197
Diagnoselinse wöhlk PAUL MAS	Ila	Diagnoselinse wöhlk MAS	HD 1566826-1 NB 0197
EGO_as	Ila	N/A	HD 1566826-1 NB 0197
EGO_as 2	Ila	N/A	HD 1566826-1 NB 0197
EGO_as 2 BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_as 2 BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_as 2 RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_as 2 VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_as BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_as BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_as RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_as VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo as	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo as 2	Ila	N/A	HD 1566826-1 NB 0197

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
EGO_bifo as 2 BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo as 2 BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo as 2 RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo as 2 VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo as BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo as BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo as RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo as VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo mas	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo mas BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo mas BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo mas RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo mas VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo s 2k	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo s 2k BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo s 2k BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo s 2k RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo s 2k VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo s 3k	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo s 3k BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo s 3k BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo s 3k RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_bifo s 3k VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_ke	Ila	N/A	HD 1566826-1 NB 0197
EGO_ke BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_ke BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_ke RT	Ila	N/A	HD 1566826-1 NB 0197

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
EGO_ke VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_mas	Ila	N/A	HD 1566826-1 NB 0197
EGO_mas BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_mas BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_mas RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_mas VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi as	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi as 2	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi as 2 BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi as 2 BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi as 2 RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi as 2 VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi as BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi as BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi as RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi as VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi mas	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi mas BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi mas BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi mas RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi mas VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi s 2k	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi s 2k BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi s 2k BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi s 2k RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi s 2k VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi s 3k	Ila	N/A	HD 1566826-1 NB 0197

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
EGO_multi s 3k BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi s 3k BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi s 3k RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi s 3k VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi FEN	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi FEN BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi FEN RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_multi FEN VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_oke	Ila	N/A	HD 1566826-1 NB 0197
EGO_oke RPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_s 2k	Ila	N/A	HD 1566826-1 NB 0197
EGO_s 2k BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_s 2k BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_s 2k RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_s 2k VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_s 3k	Ila	N/A	HD 1566826-1 NB 0197
EGO_s 3k BT	Ila	N/A	HD 1566826-1 NB 0197
EGO_s 3k BTK	Ila	N/A	HD 1566826-1 NB 0197
EGO_s 3k RT	Ila	N/A	HD 1566826-1 NB 0197
EGO_s 3k VPT	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft BIO	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft BIO TD	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft BIO TDS	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft BIO TP	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft multi BIO	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft multi BIO TD	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft multi BIO TDS	Ila	N/A	HD 1566826-1 NB 0197

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
EGO_soft multi BIO TP	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft multi SH	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft multi SH TD	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft multi SH TDS	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft multi SH TP	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft SH	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft SH TD	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft SH TDS	Ila	N/A	HD 1566826-1 NB 0197
EGO_soft SH TP	Ila	N/A	HD 1566826-1 NB 0197
Eigenmarke Vitafilcon A spheric	Ila	N/A	HD 1566826-1 NB 0197
Eigenmarke Vitafilcon A toric 2	Ila	N/A	HD 1566826-1 NB 0197
wöhlk AS	Ila	N/A	HD 1566826-1 NB 0197
wöhlk AS 2	Ila	N/A	HD 1566826-1 NB 0197
wöhlk AS 2 BT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk AS 2 BTK	Ila	N/A	HD 1566826-1 NB 0197
wöhlk AS 2 RT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk AS 2 VPT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk AS BT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk AS BTK	Ila	N/A	HD 1566826-1 NB 0197
wöhlk AS RT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk AS VPT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk BIFO AS	Ila	N/A	HD 1566826-1 NB 0197
wöhlk BIFO AS 2	Ila	N/A	HD 1566826-1 NB 0197
wöhlk BIFO AS 2 BT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk BIFO AS 2 BTK	Ila	N/A	HD 1566826-1 NB 0197
wöhlk BIFO AS 2 RT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk BIFO AS 2 VPT	Ila	N/A	HD 1566826-1 NB 0197

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
wöhlk BIFO AS BT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk BIFO AS BTK	Ila	N/A	HD 1566826-1 NB 0197
wöhlk BIFO AS RT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk BIFO AS VPT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk bifo S 2K	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk bifo S 2K BT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk bifo S 2K BTK	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk bifo S 2K RT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk bifo S 2K VPT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk bifo S 3K	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk bifo S 3K BT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk bifo S 3K BTK	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk bifo S 3K RT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk bifo S 3K VPT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk Eigenmarke Advance spheric	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk Eigenmarke Advance toric	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk Eigenmarke bio 30 spheric	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk Eigenmarke bio 30 toric	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk Eigenmarke Premium spheric	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk Eigenmarke Premium toric	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk Geaflex 70	Ila	N/A	HD 1566826-1 NB 0197
wöhlk KE	Ila	N/A	HD 1566826-1 NB 0197
wöhlk KE BT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk KE BTK	Ila	N/A	HD 1566826-1 NB 0197
wöhlk KE RT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk KE VPT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI AS	Ila	N/A	HD 1566826-1 NB 0197

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
wöhlk MULTI AS 2	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI AS 2 BT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI AS 2 BTK	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI AS 2 RT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI AS 2 VPT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI AS BT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI AS BTK	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI AS RT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI AS VPT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI FEN	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI FEN BT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI FEN RT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI FEN VPT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI S 2K	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI S 2K BT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI S 2K BTK	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI S 3K	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI S 3K BT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI S 3K BTK	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI S 3K RT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTI S 3K VPT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTli S 2K VPT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk MULTli S 2K RT	Ila	N/A	HD 1566826-1 NB 0197
wöhlk OKE	Ila	N/A	HD 1566826-1 NB 0197
wöhlk OKE RPT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk S 2K	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk S 2K BT	Ila	N/A	HD 1566826-1 NB 0197

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
Wöhlk S 2K BTK	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk S 2K RT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk S 2K VPT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk S 3K	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk S 3K BT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk S 3K BTK	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk S 3K RT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk S 3K VPT	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk Weflex 55	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk Weflex 55 toric	Ila	N/A	HD 1566826-1 NB 0197
Wöhlk Weflex 55 toric Advance	Ila	N/A	HD 1566826-1 NB 0197
wöhlk BIFO PAUL MAS	Ila	wöhlk BIFO MAS	HD 1566826-1 NB 0197
wöhlk BIFO PAUL MAS BT	Ila	wöhlk BIFO MAS BT	HD 1566826-1 NB 0197
wöhlk BIFO PAUL MAS BTK	Ila	wöhlk BIFO MAS BTK	HD 1566826-1 NB 0197
wöhlk BIFO PAUL MAS RT	Ila	wöhlk BIFO MAS RT	HD 1566826-1 NB 0197
wöhlk BIFO PAUL MAS VPT	Ila	wöhlk BIFO MAS VPT	HD 1566826-1 NB 0197
wöhlk MULTI PAUL MAS	Ila	wöhlk MULTI MAS	HD 1566826-1 NB 0197
wöhlk MULTI PAUL MAS BT	Ila	wöhlk MULTI MAS BT	HD 1566826-1 NB 0197
wöhlk MULTI PAUL MAS BTK	Ila	wöhlk MULTI MAS BTK	HD 1566826-1 NB 0197
wöhlk MULTI PAUL MAS RT	Ila	wöhlk MULTI MAS RT	HD 1566826-1 NB 0197
wöhlk MULTI PAUL MAS VPT	Ila	wöhlk MULTI MAS VPT	HD 1566826-1 NB 0197
wöhlk PAUL MAS BT	Ila	wöhlk MAS BT	HD 1566826-1 NB 0197
wöhlk PAUL MAS BTK	Ila	wöhlk MAS BTK	HD 1566826-1 NB 0197
wöhlk PAUL MAS RT	Ila	wöhlk MAS RT	HD 1566826-1 NB 0197
wöhlk PAUL MAS VPT	Ila	wöhlk MAS VPT	HD 1566826-1 NB 0197
wöhlk PAUL MAS	Ila	wöhlk MAS	HD 1566826-1 NB 0197
ZEISS CD 30 Compatic spheric	Ila	N/A	HD 1566826-1 NB 0197

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
ZEISS CD 30 Compatic toric	Ila	N/A	HD 1566826-1 NB 0197
ZEISS Contact Day 1 multifocal	Ila	N/A	HD 1566826-1 NB 0197
ZEISS Contact Day 1 spheric	Ila	N/A	HD 1566826-1 NB 0197
ZEISS Contact Day 1 toric	Ila	N/A	HD 1566826-1 NB 0197

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/06/03	WOEHL_CL607_2024-06-03	Initial issue
YYYY/MM/DD	XXXXXXXXXX	Addition of device XYZ to the list
YYYY/MM/DD	XXXXXXXXXX	Removal of device XYZ to the list