Manufacturers Declaration 2023/607

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to:

- The validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- The compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Technical File Number: LF-SG-136-STED

Reference to Product Torsional OZIL™ HP

Manufacturer:

Name: Alcon Laboratories, Inc.
Address: 6201 South Freeway
Fort Worth
Texas 76134-2099, USA

SRN: US-MF-000016248

Authorized Representative in the European Community:

Name: Alcon Laboratories Belgium
Address: Lichterveld 3
2870 Puurs-Sint-Amands
Belgium

SRN: BE-AR-000014721

Device (Trade Name)	Mold/FID Catalogue Number	GMDN Code	MDD Risk Class	Basic UDI-DI (B-UDI)
Ozil Torsional Ultrasound Handpiece	8065750469	34900	IIb	038065GMN000068HD
Ozil Torsional Ultrasound Handpiece	8065751587	34900	IIb	038065GMN000068HD

Alcon as the manufacturer declares under its sole responsibility:

For the below listed Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the Regulation (EU) 2017/745 are met

Directive Certificate number: G1 020895 0393
Original expiry date: 26-May-2024
End date of extended validity / transition period: 31-Dec-2028
Notified Body: TÜV SÜD Product Service GmbH
Identification number: 0123
Address: Ridlerstraße 65 • 80339 Munich • Germany

And, for the devices listed above, Alcon as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service.

Digitally signed by Dicusar Vladimir
Date: 2024.07.11 15:59:44 EEST
Reason: MoldSign Signature
Location: Moldova

Namely by fulfilling the following conditions:

Directive Certificate(s) covering the listed device(s) were issued after 25 May 2017, and were valid on 26 May 2021 and have not been withdrawn afterwards.

- ✓ Directive Certificate expires after 20 March 2023:
- ✓ Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made for the devices listed.
- ✓ Signed written agreement(s) are in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.
- ✓ A QMS in accordance with Article 10(9) MDR is in place.

Devices as listed:

- ✓ Continue to comply with the MDD.
- ✓ There are no significant changes in the design and intended purpose.
- ✓ Do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Place of Issue and Date: Alcon Laboratories, Incorporated, Fort Worth, TX 76134-2099 USA	Signature: Baker, Stephanie Digitally signed by Baker, Stephanie DN: cn=Baker, Stephanie, ou=PDF Internal Signing, o=Alcon Vision, LLC Date: 2024.05.29 16:50:36 -05'00' Stephanie Baker, VP Global Regulatory Affairs, Surgical & Vision Care