Torsional (OZIL)® HP, LF-SG-136-STED

DECLARATION OF CONFORMITY

(check all additional conformity route(s) based on EU MDD Article 11 requirements for the device class and specifics)

Annex II (3) ☒ Annex II (4) ☐	Annex III ☐ Annex IV ☐	Annex V ☐ Annex VI ☐	Annex VII ☐

Technical File Number: LF-SG-136-STED

Device Trade Name: Torsional (OZIL)® HP

Supersedes (Date): 27-APR-2020

Manufacturer: Alcon Laboratories, Incorporated

Address: 6201 South Freeway, Fort Worth, TX 76134-2099, USA

Authorized Representative in the European Community:

Alcon Laboratories Belgium

Address: Lichterveld 3, 2870 Puurs-Sint-Amands, Belgium

Medical Device (Trade Name)	GMDN Code	Catalogue Number	Class
ASSY, Ship, OZil HP	34900	8065750469	IIb

The device(s) covered by this declaration are in conformity with the European Medical Devices Directive 93/42/EEC as well as other, relevant Union legislation that make provisions for the issuing of a declaration of conformity as listed.

Alcon Laboratories, Incorporated. hereby declares under its sole responsibility that the listed device(s) and Quality Systems conform(s) to:

EU MDD 93/42/EEC *as amended*

This Declaration is applicable to all products listed and released after the Date of Issuance of this Declaration of Conformity, and until a revised Declaration of Conformity is issued.

Notified Body Information: Applicable ☒ Not Applicable ☐

Conformity Assessment Certificate Number(s): G1 020895 0393

Conformity Certificate Validity Period: Valid from 05-FEB-2021 Valid until 26-MAY-2024

Notified Body: TÜV SÜD Product Service GmbH

Identification number: 0123

Address: Ridlerstraße 65, 80339 Munich, Germany

Place of Issue:	Date of Issue:	
Lake Forest, CA, USA	25-APR-2021	Regis, Kim Digitally signed by Regis, Kim DN: cn=Regis, Kim, ou=PDF Internal Signing, o=Alcon Vision, LLC Date: 2021.04.25 15:16:54 -07'00' Adobe Acrobat DC version: 2015.006.30493 Name/Title/Function/Date: Kim Regis/Sr. Director/GRA Surgical Instrumentation

Digitally signed by Dicusar Vladimir
Date: 2024.07.11 15:59:30 EEST
Reason: MoldSign Signature
Location: Moldova