

DECLARATION OF CONFORMITY

We, Haag-Streit UK,

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Declare under our sole responsibility that the product(s) listed below to which this declaration relates, is in conformity with the applicable provisions as required by Part II of UK Medical Devices Regulations 2002 (as amended) for general medical devices according to Annex V (as modified by Part II of Schedule 2A to the UK MDR 2002) audit of the production quality assurance system.

Device Group: Tonosafe Sterile Disposable Prism

Description: Refer to Product Schedule on page 2 onwards for a complete list of part codes and descriptions

Intended Purpose: Tonosafe is intended for use as disposable applanating and optical doubling prisms for use with Goldmann and Perkins Tonometers. The device is used to measure the intraocular pressure (IOP) of the eye. This measurement is used in the diagnosis of various eye diseases such as Glaucoma.

Risk Classification: The device(s) has been classified as **class IIa, Rule 5** in accordance with Part II of the UK MDR 2002, Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2002).

The accessories have been classified as **Class I, Rule 1** in accordance with Part II of the UK MDR 2002, Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2002).

The UK Approved Body responsible for carrying out those elements of the regulation requiring authorised body intervention is SGS United Kingdom Ltd (Approved Body #0120 Certificate No GB22/00000250), Inward Way, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, United Kingdom

Designated Standards: Refer to HSHS2015393 for a complete list of applied standards

Authorised By:


Signed: [guerino ostacchini \(Jun 7, 2023 10:01 GMT+1\)](#)

Date: 07 June 2023

Mr G Ostacchini

Managing Director (Operations)

Signed: 

Date: 05 June 2023

Kerrie Mouncey

QA/RA Manager

	Doc N° DCHS20221822	V 4	Page 2 of 2
	Title; UK MDR Declaration of Conformity – Tonosafe Sterile Disposable Prism		

Product Schedule

Description	Part Code	GMDN	GTIN
Tonosafe – Class IIa			
TONOSAFE 100 PRISM/BOX	5805100	62405	0506 0179 4705 59
BOX OF 20 TONOSAFE & 1 HOLDER	5805091	62405	0505 6158 0002 44
Device Accessories – Class I			
PRISM HOLDER PACK	5805084PACK	66690	0505 6158 0018 38