DECLARATION OF CONFORMITY

We, Haag-Streit UK,
Unit C, Woodside Industrial Estate,
Dunmow Road, Bishop's Stortford,
Hertfordshire CM23 5RG,
United Kingdom
Tel: +44 (0) 1279 414969
Email: Regulatoryhsuk@haag-streit-uk.com

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 II excluding section 4 (as modified by Part II of Schedule 2A to the UK MDR 2002) audit of full quality assurance system.

Device Group: Tonometer Systems

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

Intended Purpose: An ophthalmic, battery-powered, reusable measuring instrument with reusable calibration weights and a limited reuse (100 processing cycles or 2 years) prism.

Risk Classification: The device(s) has been classified as **class IIa**, **Rule 10** 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 HSHS2017913 for a complete list of applied standards

Authorised By:

Signed: guerino ostacchini (Jun 22, 2023 09:13 EDT)
Date:
Mr G Ostacchini   22 Jun 2023
Managing Director (Operations)

Signed: Kerrie Mouncey (Jun 22, 2023 14:09 GMT+1)
Date:
Kerrie Mouncey   22 Jun 2023
QA/RA Manager

Description	Part Code	GMDN	GTIN
Perkins Tonometer MK3 (UK)	5806000A	16809	05060179470184 (Tonometer)
Perkins MK3 UK (Tonosafe)	5806001A	16809	05060179470238 (Tonometer)
Perkins Tonometer MK3 (EU)	5806001B	16809	05060179470191 (Tonometer)
Perkins MK3 Jap/Can	5806003	16809	05060179470221 (Tonometer)
Perkins MK3 Aus	5806004	16809	05060179470207 (Tonometer)
Perkins MK3 China	5806005	16809	05060179470214 (Tonometer)