

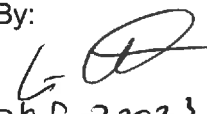
**DECLARATION OF CONFORMITY**

**We, Haag-Streit UK,**  
Unit A, Cartel Business Estate,  
Edinburgh Way, Harlow  
Essex, CM20 2TT  
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 V Sterility aspects only (as modified by Part II of Schedule 2A to the UK MDR 2002) audit of the production quality assurance system.

- Device Group:** Schirmer Tear Test
- Description:** Refer to Product Schedule on page 2 onwards for a complete list of part codes and descriptions
- Intended Purpose:** A small adsorbent strip, made of filter paper or similar material, which is manually inserted under the patient's lower eyelid for a period of time to stimulate and evaluate the formation of tears.
- Risk Classification:** The device(s) has been classified as **class Is, 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 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 GB22/00000251), Inward Way, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, United Kingdom
- Designated Standards:** Refer to **HS2016675** for a complete list of applied standards.

Authorised By:

Signed:   
Date: 13<sup>th</sup> Feb 2023  
Mr G Ostacchini  
Managing Director (Operations)

Signed:   
Date: 13 Feb 2023.  
Kerrie Mouncey  
QA/RA Manager



**HAAG-STREIT  
UK**

Doc N° DCHS20231944

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Title; UK MDR Declaration of Conformity – Schirmer  
Tear Test

<b>Description</b>	<b>Part Code</b>	<b>GMDN</b>	<b>GTIN</b>
SCHIRMER TEAR TEST, PACK OF 50	4701001	37863	05060179470726