

Declaration of Conformity – Microscope Accessories

Manufacture: Haag-Streit AG
 Gartenstadtstrasse 10
 3098 Koeniz, Switzerland
 Email: regulatory@haag-streit.com

We declare under our sole responsibility that the product(s) listed to which this declaration relates, is in conformity with the applicable provisions of Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Device group: Microscope

Device description: Microscope Accessories

REF	Description	Sales Number
4000044	Lever 10D x 35 for EIBOS 2	7700044
4000045	Lever 8D x 18 for EIBOS 2	7700045
4000048	Ophthalmoscopic lens 90D for EIBOS 2	7700048
4000049	Ophthalmoscopic lens SPXL for EIBOS 2	7700049
4000050	Set of sterilizable caps HS Hi-R NEO 900	7700050
4000051	Silicon cover for EIBOS 2	7700051
4000052	Silicon cover for handles of microscope Hi-R 900/900A S/N <5000	7700052
4000053	Silicon cover for handles of microscope Hi-R 900/900A S/N >5000	7700053
628 141	Cap 8 D x 18 on RR for microscope HS Hi-R NEO 900	2210266S
628142	Cap 12D x 19 on RR for microscope HS Hi-R NEO 900	2001326S
628114	Cap 12D x 30 for microscope HS Hi-R NEO 900	2210264S
628136	Lever 10 D x 36 for EIBOS	2210264S
628137	Silicon cover for EIBOS	2001319S

Risk classification in accordance with Annex VIII:

The device(s) have been classified as Class I Accessory, in accordance with Annex VIII EU Medical Device Regulation 2017/745.

Classification: **Class I – Accessories**

Rule according to Annex VIII: **Rule 1** – Applicable, Non-Invasive, Non-active medical device

The General Safety and Performance Requirements is achieved by application of Common Specifications, Applied Standards and Guidance documents. These are available upon request.

Conformity Assessment Procedure Annex II + III

HAAG-STREIT AG

Gartenstadtstrasse 10
 CH-3098 Koeniz, Switzerland
 Phone: +41 31 978 01 11, Fax: +41 31 978 02 90
 info@haag-streit.com, www.haag-streit.com

EU Authorised Representative:

Haag-Streit Deutschland GmbH
SRN DE-AR-000025462
22880 Wedel, Germany

Authorised By:

Signed: 

Date: 15 Oct 2024

Mr E. Verstegen
Head Quality Management and
Regulatory Affairs

Signed: 

Date: 15 Oct 2024

Kerrie Mouncey
QA/RA Manager

HAAG-STREIT AG

Gartenstadtstrasse 10
CH-3098 Koeniz, Switzerland
Phone: +41 31 978 01 11, Fax: +41 31 978 02 90
info@haag-streit.com, www.haag-streit.com