



Declaration of Conformity - BI 900

We declare under our sole responsibility that the medical device **Slit Lamp BI 900** and its accessories complies with all applicable provisions of Regulation 2017/745 (MDR). Compliance with the General Safety and Performance Requirements is achieved by application of international standards listed in the document "Applied Standards".

Intended Use

A slit lamp biomicroscope is intended for use in eye examination. It is used to aid in the diagnosis and documentation of diseases or trauma which affect the structural properties of the eye.

Manufacturer	Haag-Streit AG SRN CH-MF-000020981 CHRN-MF-20000022 3098 Koeniz, Switzerland
EU Authorized Representative	Haag-Streit Deutschland GmbH SRN DE-AR-000025462 22880 Wedel, Germany

Medical Device

Name	Slit Lamp BI 900
Part Number	1022197
Basic UDI-DI	764013298Slit_LampMT
Class & Rule according Annex VIII	I, 10
Conformity Assessment Procedure	Annex II+III

Accessories

Name, Part Number	Headrest HR-A (with lower part RAL 7035), 1420181 Headrest HR-A (with lower part silver), 1420182 Headrest HR-A (with lower part RAL 9005), 1420183 Headrest HR-D (with lower part silver), 1420186 Headrest HR-D (with lower part RAL 7035), 1420187 Headrest HR-K (with lower part for adapter RAL 7035), 1420191 Headrest HR-E (for pendulum table RAL 7035), 1420193 Headrest HR-E (for pendulum table silver), 1420194 Headrest HR-O (with lower part for adapter RAL 7035), 1420200 Headrest HR-F (without lower part silver), 1420201 Headrest HR-F (without lower part RAL 7035), 1420202 Headrest HR-G (without lower part silver), 1420203 Headrest HR-G (without lower part RAL 7035), 1420204 Headrest HR-M (without lower part silver), 1420205 Headrest HR-M (without lower part RAL 7035), 1420206 Headrest HR-A (with lower part), 1021554
Basic UDI-DI	764013298Slit_Lamp_AccsAG

Class & Rule according
Annex VIII I, 1

Conformity Assessment
Procedure Annex II+III

Declaration of Conformity is valid until **06/2028**



Köniz, 12.06.2023
Place and Date of Issue

Eric Verstegen
Head Quality Management and
Regulatory Affairs

Jörg Breitenstein
Head Research and Development