

EU Declaration of Conformity

Manufacturers Name: Haag-Streit Surgical GmbH & Co. KG

Manufacturers Address: Rosengarten 10
D-22880 Wedel
Germany

SRN (Single Registration Number): Pending

Name of the Device(s): HS Surgical Microscope

Basic UDI-DI: See product list continued overleaf

Product code (REF): See product list continued overleaf

Classification: I

Conformity assessment route: Haag-Streit Surgical GmbH & Co. KG applies the following procedures for the CE labeling of their products according to the Regulation (EU) 2017/745:

Class I: EU conformity declaration according to annex II & annex III

Considered harmonized standards / common specifications: EN 60601-1:2013 – Medical electrical equipment – Part 1: General requirements for safety and essential performance
EN 60601-1-2:2015 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
EN ISO 14971:2012 – Medical devices – Application of risk management to medical devices

Haag-Streit Surgical GmbH & Co. KG is the manufacturer of the above-mentioned products and is solely responsible for issuing this declaration of conformity.

We hereby declare that the medical device(s) specified above complies / comply with the General Safety and Performance Requirements stated in annex I of the Regulation (EU) 2017/745 and that the medical device(s) meets / meet the provisions of the Directive 2011/65/EU (RoHS). This declaration is supported by the Quality System approval to ISO 13485 issued by TÜV SÜD Product Service GmbH.

Place, date: Wedel, 09.06.2021



Dr.-Ing. S. Kaufmann
Director Research and Development

L. Hülsebusch
Director Quality Management & Regulatory Affairs

Valid until: 09.06.2024

HS Operationsmikroskope
HS Surgical Microscopes

Produkt / Device	Ident-Nr. / REF	Basis-UDI-DI / Basic UDI-DI
HS ALLEGRA SERIE / HS ALLEGRA SERIES		
HS ALLEGRA 900	657H591	++EMWM657H591W2
HS ALLEGRA 500	657H551	++EMWM657H551VN
HS ALLEGRA 330	657H553	++EMWM657H553VS
HS ALLEGRA 90	657H580	++EMWM657H580VV
HS ALLEGRA 590	657H582	++EMWM657H582VZ
HS Hi-R SERIE / HS Hi-R SERIES		
HS Hi-R NEO 900	657 820	++EMWM657820SM
HS Hi-R NEO 900A	657 821	++EMWM657821SP
HS Hi-R NEO 900A NIR	657 822	++EMWM657822SR
HS Hi-R 700	657H702	++EMWM657H702VK
HS Hi-R 700XY	657H704	++EMWM657H704VP
HS Hi-R NEO 700	657 901	++EMWM657901SN
HS Hi-R NEO 700XY	657 902	++EMWM657902SQ
HS Hi-R 1000	656H950	++EMWM656H950VV