

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 Carrying Systems for Surgical Microscopes

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:

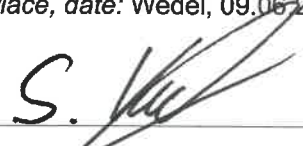
Class I: EU conformity declaration according to annex II & annex III

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 Trägersysteme für Operationsmikroskope
HS Carrying Systems for surgical microscopes

Produkt / Device	Ident-Nr. / REF	Bais-UDI-DI / Basic UDI-DI
Bodenstative / Mobile floor stands		
FS 1-12	615H450	++EMWM615H450T5
FS 2-11	615H511	++EMWM615H511SY
FS 2-15	615H515	++EMWM615H515T8
FS 2-21	615H510	++EMWM615H510SW
FS 2-23	615H523	++EMWM615H523T7
FS 2-25	615H550	++EMWM615H550TA
FS 3-43	615H703	++EMWM615H703TB
FS 3-45	615 705	++EMWM615705QS
FS 5-33	616 803	++EMWM616803R2
Deckeneinheiten / Ceiling units		
CU 3-51	607 001	++EMWM607001PJ
CU 3-55	607 005	++EMWM607005PS