

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 Accessories for Surgical Microscope Systems

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:

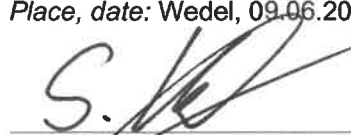
Class I: EU conformity declaration according to annex II & annex III

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 Zubehör / Operationsmikroskop-Systeme

HS Accessories / Surgical Microscope Systems

Produkt / Device	Ident-Nr. / REF	Basis-UDI-DI / Basic UDI-DI
Beobachtungssysteme / Observation modules		
Beam Splitter 50:50	657 260	++EMWM657260S3
Beam Splitter T	657H165	++EMWM657H165VD
DIPLOSCOPE U	657H029	++EMWM657H029V4
DIPLOSCOPE T-R	657H040	++EMWM657H040UQ
VERTISCOPE U	657H028	++EMWM657H028V2
VERTISCOPE T-L	657H022	++EMWM657H022UN
VERTISCOPE T-R	657H027	++EMWM657H027UY
VERTISCOPE	657H017	++EMWM657H017UV
C.DUO	657 182	++EMWM657182S8
C.INJECT 900	657 187	++EMWM657187SJ
C.INJECT 1000	657 186	++EMWM657186SG
Imaging System und Kameras / Imaging System and Cameras		
HS MIOS 5	616 660	++EMWM616660R4
C.MOR HD	196 614	++EMWM196614RL
C.MOR HD ³	196 814	++EMWM196814RW
Kameraansätze / Camera Attachments		
Camera attachment 1/3" C-Mount (micro)	657H081	++EMWM657H081V6
Camera attachment 1/2" C-Mount (micro)	657H076	++EMWM657H076VD
Camera attachment 1/3" C-Mount	656H715	++EMWM656H715VH
Camera attachment 1/2" C-Mount	656H710	++EMWM656H710V7
Monitore und Displays / Monitors and Displays		
C.MON HD	196 820	++EMWM196820RR
M.DIS for HS Hi-R NEO 900/900A	657H370	++EMWM657H370VG
M.DIS for HS Hi-R 700 and HS Hi-R 700XY/1000	657H375	++EMWM657H375VS
M.DIS HS Hi-R NEO	657 344	++EMWM657344SA
Einblicke und Mitbeobachter / Eyepieces and stereoscopic observers		
Einblick / Eyepiece head 160°, inclin., 10x oculars - spindle	656H672	++EMWM656H672VQ
Einblick / Eyepiece head, 200°, inclin., 10x oculars	656H935	++EMWM656H935VZ
Einblick / Eyepiece head 0°, 12.5x	655 500	++EMWM655500RJ
Stereoskopischer Mitbeobachter / Stereoscopic observer head, w. 160° eyepiece head, 10x, spindle	654 371	++EMWM654371RQ
Stereoskopischer Mitbeobachter / Stereoscopic observer head, fix 0° eyepiece head, 12.5x	654H359	++EMWM654H359UT
Fußschalter / Foot switches		
EF 5000	615H752	++EMWM615H752TQ
EF 5001	615H753	++EMWM615H753TS
Foot switch PEDDY w. 2 functions (focus)	122 502 83	++EMWM12250283MV
Weiteres Zubehör / Additional Accessories		
Irisblende / Double iris diaphragm	654 340	++EMWM654340RD
MAGNIFEYE	657H155	++EMWM657H155VA
TOCULAR	657H230	++EMWM657H230UX
XL 2-23	615H525	++EMWM615H525TB
EIBOS 2 (f = 175 mm)	657H600	++EMWM657H600VA
EIBOS 2 (f = 200 mm)	657H601	++EMWM657H601VC
EIBOS 2 NIR (f = 175 mm)	657H602	++EMWM657H602VE

HS Zubehör / Operationsmikroskop-Systeme
HS Accessories / Surgical Microscope Systems

EIBOS 2 NIR (f = 200 mm)	657H603	++EMWM657H603VG
Ophthalmoscopic lens 90D NIR	657 693	++EMWM657693T6
Ophthalmoscopic lens SPXL NIR	657 694	++EMWM657694T8
Ophthalmoscopic lens 90D	657 695	++EMWM657695TA
Ophthalmoscopic lens SPXL	657 696	++EMWM657696TC
EIBOS 2 suitable for Zeiss	657H608	++EMWM657H608VS

