CooperSurgical

Document Number: DoC002 Issue: C Date: 10 January 2022

EC Declaration of Conformity

(for EU & RoW)

PRODUCT IDENTIFICATION	
LEISEGANG COLPOSCOPE AND ACCESSORIES	
GMDN Name: GMDN Name – Colposcope	**GMDN Code:** 10960
CND 2018 CODE Description: COLPOSCOPI	**CND Code:** Z12020703
EMDN Description: COLPOSCOPI / Colposcopes	**EMDN Code:** Z12020703
List of UDI Device Identifiers:	**BASIC UDI-DI / GMN Number:** 42601TD002FY For UDI DI / GTINs, see List in Appendix 1
Intended Purpose	Leisegang colposcopes are used in gynecological examinations to provide enlarged, non-contact view of the outer female genitalia (vulva, vagina, portio) in the visible area. The colposcopes can also be used for enlarged, non-contact viewing of other external organs. Leisegang photo/video colposcopes with an integrated or externally connected camera can also be used to document the findings. Leisegang colposcopes are only used to aid in the diagnosis. In any case, further findings are to be consulted.

MANUFACTURER		
Name of Company	**Address**	**Representative**
Leisegang Feinmechanik-Optik GmbH	Leibnizstr. 32, 10625 Berlin, Germany	Claudia Brakop, Senior Head Quality Assurance and Regulatory Affairs
Single Registration Number (SRN): DE-MF-000006525		

REGISTRATION INFORMATION	
Notified Body and ID #	**CE Certificate Number**
Not applicable Self-Certified	Not applicable

CONFORMITY ASSESSMENT		
Device Classification	**Route to Compliance**	**Standards Applied**
Class I Rule 13 (All other active Devices)	Article 19 and Annexes II and III of regulation MDR (EU) 2017/745	See Appendix 1.

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Leisegang Feinmechanik-Optik GmbH hereby declares under our exclusive responsibility the above-mentioned products meet the relevant provisions of the European Regulation (EU) 2017/745 for Medical Devices and those General Safety and Performance Requirements listed in Annex I; also, any applicable standards and related European Union legislation reflected in the two (2) tables of Appendix 2 and 3.
The medical device Leisegang colposcope with the below mentioned model number consist of the power supply unit REF B6400 / LED Y/C.

The conformity of the device is confirmed through placement of the CE Mark on each device. All supporting documentation is retained under the premises of the manufacturer.

REPRESENTATIVE NAME: Claudia Brakop

TITLE: Senior Head Quality Assurance and Regulatory Affairs

SIGNATURE: C Brakop

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Appendix 1: List of Models, Model Numbers, UDI DI, Serial Number and higher, manufactured before November 2024

PRODUCT IDENTIFICATION			
Product Name (Colposcope Model)	**Model Number**	**UDI DI (GTIN)**	**Up from Serial Number**
Standard Colposcopes			
1D LED	1D-121100	4260187790033	21-030001
1E LED	1E-111100	4260187790019	21-010001
1DS LED	1DS-131100	4260187790040	21-040001
1DW LED	1DW-221100	4260187790057	21-032001
1DL LED	1DL-LED	4260187790064 (US)	21-041001
1D LED	1D	N/A (RUS)	21-111001
1E LED	1E	N/A (RUS)	21-114001
1DS LED	1DS	N/A (RUS)	21-112001
1DW LED	1DW	N/A (RUS)	21-113001
Photo/Video Colposcopes			
3ML LED	3ML-121100	4260187790071	21-050001
3MLS LED 1"	3MLS 1"-131105	4260187790095	21-080001
3MLS LED ½"	3MLS ½" -131103	4260187790101	21-082001
3MLW LED	3MLW-221100	4260187790125	21-051001
3MVC LED USB	3MVC-121112	4260187790132	21-070001
3MVCW LED USB	3MVCW-221112	4260187790156	21-071001
3MVCS LED USB	3MVCS-131112	4260187790149	21-095001
3MVCL LED USB	3MVCL-131112	4260187790170 (US)	21-096001
3MTL LED 1"	3MTL-LED 1"	4260187790163 (US)	21-081001
3ML LED	3ML-121100	N/A (CHN)	21-052001
3ML LED	3ML LED	N/A (RUS)	21-116001
3MLS LED 1"	3MLS LED 1"	N/A (RUS)	21-117001
3MLS LED ½"	3MLS LED ½"	N/A (RUS)	21-118001
3MLW LED	3MLW LED	N/A (RUS)	21-119001
3MVC LED USB	3MVC LED USB	N/A (RUS)	21-120001
3MVCW LED USB	3MVCW LED USB	N/A (RUS)	21-122001
3MVCS LED USB	3MVCS LED	N/A (RUS)	21-121001
Power Supply (Part of the Colposcope Head)			
Power supply complete – 3,2 V 3A CE/UL	B0006400	4260187790309	21-530001

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Product Name (Stand Model)	Model Number	UDI DI (GTIN)	Up from Serial Number
Stands (Accessories)			
Upright-Stand complete	BG000130	4260187790231	21-250001
Upright-Stand complete with 5-wheel spider base	BG000131	4260187790361	21-255001
Tilt stand	BG000175	4260187790231	21-260001
Swing-o-matic stand for heavy 5-wheel spider base	BG001530	4260187790194	21-200001
Swing-o-matic stand without pillar for examination chair	BG000160	4260187790224	21-210001
Swing-o-matic stand with long pillar for examination chairs	BG000180	4260187790200	21-230001
Swing-o-matic stand with short pillar for examination chair	BG000170	4260187790217	21-220001
Balance-o-matic stand model 1-3	BG000135	4260187790248	21-240001

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Appendix 2: List of Harmonized Standards, Common Specifications, other relevant EU legislation

Identification Number	Title or Description	Version or Year
EN ISO 13485	QMS for the Design & Manufacture of Medical Devices	2016
EN ISO 14971	Risk Management for Medical Devices	2019
EN 1041 EN +A1	Information to be supplied with Each Medical Device Sold in Europe	2013
EN ISO 15223-1	Symbols to be used with Medical Device Labels, Labelling & Information	2016
ISO 15223-1	Symbols to be used with Medical Device Labels, Labelling & Information	2021
EN 60601-1 EN +A1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2013
EN 60601-1-1	Medical electrical equipment - Part 1-1: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems	2002
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	2016
EN 60601-1-6 EN +A1	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	2015
EN 60601-2-41 EN +A1	Medical electrical equipment - Part 1-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis.	2015
EN 62366-1	Medical devices — Part 1: Application of usability engineering to medical devices	2015
EN 62353	Medical electrical equipment Recurrent test and test after repair of medical electrical equipment	2014
EN 62304 EN +A1	Medical device software - Software life-cycle processes	2015
EN ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical practice	2020
EC 1907/2006 REACH	Regulation (EC) No 1907/2006 - Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) in the current version	2006
EU 207/2012	Regulation (EU) No 207/2012 on electronic instructions for use of medical devices	2012
RoHS II EG Directive 2011/65/EU	Restriction of Hazardous Substances Directive	2011
Commission Delegated Directive 863	COMMISSION DELEGATED DIRECTIVE (EU) 863 amending Annex II to Directive 65/EU of the European Parliament and of the Council as regards the list of restricted substances	2015
REACH SVHC Regulation (EC) No. 1907/EU	Registration, Evaluation, Authorization and Restriction of Chemicals – Substances of Very High Concern	2006
WEEE Directive 1212/19/EU	The Waste Electrical and Electronic Equipment Directive (WEEE Directive)	2012

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Appendix 3: List of other relevant legislation, regulations, and standards

Identification Number	Title or Description	Version or Year
ISO 2859-1 +Cor.1 +A1	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	2011
21CFR Part 820	Current CFR - Code of Federal Regulations Title 21 / PART 820 QUALITY SYSTEM REGULATION	
N/A	European Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council (EU MDR)	
N/A	German Act on Medical Devices of 02 August 1994; as amended by Notice of 07 August 2002 I 3146; last amended by Art. 15 Abs. 1 G of 19 May 2020 I 1018	2020
N/A	Law to adapt medical device law to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 from 28.04.2020 (Medizinprodukte-EU-Anpassungsgesetz – MPEUAnpG)	2020
N/A	Law for the implementation of EU regulations relating to medical devices vom 28.04.2020 (Medizinprodukterecht-Durchführungsgesetz – MPDG) (Kapitel I des MPEUAnpG)	2020
N/A	Guidance - MDCG endorsed documents and other guidance https://ec.europa.eu/health/md_sector/new_regulations/guidance_en	
N/A	Current further national or EU regulations and laws relating to medical devices found at: https://www.bfarm.de/DE/Medizinprodukte/RechtlicherRahmen/gesetze/mprecht-inhalt.html	
N/A	Applicable current IMDRF (International Medical Device Regulators Forum) documents under: http://www.imdrf.org/documents/documents.asp#imdrf	
N/A	Applicable current NBOG (Notified Body Operations Group) documents under: http://www.nbog.eu/nbog-documents/	