LEISEGANG
The Colposcope Company

# *EC Declaration of Conformity for Vietnam*
*According Medical Device Directive 93/42/EEC*

| | | |
|---|---|---|
| Manufacturer: | | **Leisegang Feinmechanik-Optik GmbH**<br>**Leibnizstr. 32, D-10625 Berlin** |
| Conformity Assessment Procedure: | | **Annex VII of the Directive 93/42/EEC on Medical Devices** |
| Classification of device: | | **Class I in accordance with MDD, Annex IX, rule 12** |
| | Category: | **Colposcope** |
| Identification of the Device: | Type: | **Leisegang colposcope** |
| | UMDNS code: | **10-960** |
| | GMDN code: | **10960** |
| | Models: | **See Table** |
| | SN: | **See Table and higher,** manufactured before November 2018. |

| Model name | Model no (REF) | Serial number and higher, manufactured before November 2018 |
|---|---|---|
| Standard colposcope | | |
| 1E | 1E – 111100 | 17-010001 |
| 1D | 1D – 121100 | 17-030001 |
| 1DW | 1DW – 221100 | 17-032001 |
| Photo/video colposcope | | |
| 3ML | 3ML – 121100 | 17-050001 |
| 3MVS Y/C | 3MVS Y/C – 131131 | 17-093001 |
| 3MLW | 3MLW – 221100 | 17-051001 |
| 3MVC | 3MVC – 121112 | 17-070001 |
| 3MVCW | 3MVCW – 221112 | 17-071001 |

EC Declaration of Conformity 2017-08-07

We, the manufacturer hereby declare under our exclusive responsibility that the above mentioned devices comply with the relevant provisions of the EU Council Directive 93/42/EEC dated 14 June 1993, amended EU Council Directive 2007/47/EC dated 5 September 2007, Annex I – Essential Requirements, the applicable harmonized standards and its relevant transpositions into national laws of the Member States in which the above mentioned medical device are distributed.

The medical device **Leisegang colposcope** with the above mentioned model number consist the power supply unit REF B6400 / LED Y/C.

The list of applied and considered standards is recorded in the technical file of the medical device and the manufacturer will provide this on request.

The conformity of the device is confirmed though adjustment of the CE sign on the label of the each device.

Berlin, August 07, 2017

Uwe Skirl

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