

# Declaration of Conformity

Manufacturer:



Address:

Heidelberg Engineering GmbH  
Max-Jarecki-Straße 8  
D-69115 Heidelberg  
Germany

Products / Devices:

**SPECTRALIS Product Family -  
HRA, OCT, HRA+OCT and Accessories**

Category 8, Annex I Council Directive 2011/65/EC

We, the manufacturer herewith declare under our sole responsibility that the above mentioned product and its configurations meet the provisions of the following EC Council Directive and all amendments valid by the time of this declaration.

## DIRECTIVES

Product Conformity:

Council Directive 2011/65/EU of the European Union from June 08<sup>th</sup> 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2) (ABl. Nr. L 174 dd. July 1<sup>st</sup> 2011), supplemented by Directive 2015/863/EU (RoHS3) and last amendment Directive 2017/2102/EU (ABl. Nr. L 305) dd. November 21<sup>st</sup> 2017.

Conformity Assessment:

A complete Quality Assurance System, fulfilling the requirements of the Medical Device Regulation (EU) 2017/745, Annex IX as well as requirements of Directive 2011/65/EU (RoHS2) and amendments, has been established. Supporting documentation and evidence records are available in the Technical File of the manufacturer for the above mentioned product.

This declaration is valid for above-mentioned products, which are CE-marked after the signature date below.

Place, Date:

Heidelberg, 2020-10-06

Signature:

Name:

Position:

A handwritten signature in blue ink, appearing to read "Christa Schäfer", written over a horizontal line.

Christa Schäfer  
Head of Quality Management

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### **Annex I Applied Exception Rules of the RoHS Directives for SPECTRALIS Product Family - HRA, OCT, HRA+OCT and Accessories**

	Applicable Directive	Category	RoHS Exception No.
Art-No. 30283 SPECTRALIS OCT- Data Cable	2011/65/EU Annex III	8	6c
Art-No. 30290 SPECTRALIS HRA2- Data Cable	2011/65/EU Annex III	8	6c
Art-No. 30291 SPECTRALIS HRA2- Power Cable	2011/65/EU Annex III	8	6c
Art-No. 30292 SPECTRALIS Coax Cable	2011/65/EU Annex III	8	6c
Art-No. 30284 SPECTRALIS OCT- Power Cable	2011/65/EU Annex III	8	6c
Art.-No. 22918 SPECTRALIS Camera Mount Piston	2011/65/EU Annex III	8	6c
Art.-No. 33104 SPECTRALIS Cable Touch Screen Panel	2011/65/EU Annex III	8	6c
Art-No. 50117 SPECTRALIS Ultra Widefield Objective	2011/65/EU Annex III	8	6a, 6c