From Eye to Insight

EC Declaration of Conformity

In accordance with the provisions of the EU MDR 2017/745
For the M320 listed under certificate number 20210504-04-V01

Place and Date of issuance: **Heerbrugg, 6 May 2021**

We

Legal Manufacturer	**Leica Microsystems (Schweiz) AG** Max Schmidheiny-Strasse 201 9435 Heerbrugg, Switzerland
Legal Manufacturer SRN	**Not available**
Authorized Representative	**Leica Microsystems CMS GmbH** Ernst-Leitz-Strasse 17-37 35578 Wetzlar, Germany
Manufacturing Site (if different from Manufacturer)	**Leica Instruments (Singapore) Pte Ltd** 12 Teban Gardens Crescent Singapore 608924

declare under our sole responsibility that the following medical device:

Medical Device Brand Name	**M320**
Product Code	**35191 / 41895 (GMDN)**
Basic UDI - DI	**M320**
Classification / Rule	**Class I, Rule 1 & Rule 10**
Conformity Assessment Route	**Annex II and III**

with the intended purpose of:
The M320 surgical microscope is an optical instrument for improving the visibility of objects through magnification and illumination. It can be applied for observation and documentation and for human and medical treatment

to which this declaration relates, is in conformity with the requirements of the EU MDR 2017/745, including amendments, which apply to it.

This declaration applies to CE marked devices produced after the date of issuance of this declaration and is referenced to as:

Certificate Number:	**20210504-04-V01**
Certificate Expiry Date:	**MAY-2026**

Roland Jehle
Signature

CE

Roland Jehle
Person Responsible for Regulatory Compliance (PRRC)

Leica Microsystems (Schweiz) AG. Max Schmidheiny-Str. 201 . 9435 Heerbrugg, Switzerland . www.leica-microsystems.com
Leica Microsystems (Schweiz) AG established in Balgach | Commercial Register Office St. Gallen CHE-106.832.287
Board of Directors: Georges Hakim | Melanie Hammerschmidt-Broman | Andreas Hecker

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This conformity is based on the following list of harmonized standards and / or common standards applied for CE marking:

- EN ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971:2012 – Medical devices – Application of risk management to medical devices
- EN ISO 15223-1:2016 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
- EN ISO 17664:2017 – Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
- EN 60601-1:2006 + A1:2013 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2:2015 – Medical electrical equipment – Part 1-2: General requirements for basic and essential performance – Collateral standard: Electromagnetic compatibility
- EN 60601-1-6:2010 + A1:2015 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- EN 62304:2006 + AC:2008 + A1:2015 – Medical device software – Software life-cycle processes
- EN 62366:2008 – Medical devices – Application of usability engineering to medical devices
- EN 62471:2008 – Photobiological safety of lamps and lamp systems

End of Document

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