UK Declaration of Conformity

1. *Manufacturer and or Authorised Representatives Details*

Manufacturer
Name: Leica Microsystems CMS GmbH
Address: Ernst-Leitz-Straße 17-37,
35578 Wetzlar, Germany

UKRP
Name: Leica Microsystems (UK) Limited
Address: Larch House, Woodlands Business Park,
Milton Keynes,
England, United Kingdom, MK14 6FG

2. *This declaration is used under the sole responsibility of the manufacturer*

We hereby declare that the device described below, both in its basic design and construction and in the version marked by us, conforms to the relevant safety- and health related requirements of the appropriate UK legislations.
This declaration shall cease to be valid if modifications are made to the device without our approval.

3. *Object of the declaration*

Product:	Microscope
Model:	Visoria B Global IVD
Order no.:	11 561 611
Product class:	A (according to rule 5 Annex VIII of EU directive 2017/746)
GMDN Code:	15132 (Microscopic blood / cell examination Instruments IVD)
Basic UDI-DI:	42519697VISORIABLW (Basic Unique Device Identification)

4. *First date of UKCA compliance*

Date: April 1st 2025

5. *The products listed are in compliance with the relevant statutory requirements detailed*

Medical Device Regulations 2002 (SI 2002 No 618) Part IV In Vitro Diagnostic Medical Devices

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

6. *References to the designated standards used to which conformity is declared*

BS EN 61010-1+A1:2017	EN 61010-1:2010+A1:2019
BS EN 61010-2-101:2017	EN IEC 61010-2-101: 2022
BS EN IEC 61326-1:2021	EN 61326-1:2021
BS EN IEC 61326-2-6:2021	EN IEC 61326-2-6:2021
BS EN 62471:2009	EN 62471:2008
BS EN IEC 63000:2018	EN IEC 63000:2018

7. *Details of Approved Body*

n.a.

8. *Signed on behalf of the manufacturer by*

Name: Steffen Laabs
Job Title: RA/QA Director
Date: 21.10.2025
Signed:

Registration no. of the UKCA declaration: UK 269-1
(Leica internal)