

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:	DM IL LED Fluo Cellfactory
Order no.:	11 521 281
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:	42519697DMILLED TN (Basic Unique Device Identification)
4. First date of UKCA compliance	
Date: January 11 th 2023	
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 BS EN 61010-2-101:2017 BS EN IEC 61326-1:2021 BS EN IEC 61326-2-6:2021 BS EN 62471:2009 BS EN IEC 63000:2018	EN 61010-1:2010+A1:2019 EN 61010-2-101: 2017 EN 61326-1:2013 EN 61326-2-6:2013 EN 62471:2008 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: 11.01.2023 Signed: 