

1. Manufacturer and or Authorised Representatives Details**Manufacturer**

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

Authorized Person to compile the technical file:
Dr. Tobias Bauer, R&D Director Wetzlar

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: Ultra Microtom

Model: UC Enuity
containing: UC Enuity Processing Unit; UC Enuity Control Unit

Order no.: 16 708 001, 16 708 002, 16 708 003, 16 708 004 (starting with serial no. 638558)

4. First date of UKCA compliance

Date: January 15th 2024

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

Electromagnetic Compatibility Regulations 2016

Supply of Machinery (Safety) Regulations 2008

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 IEC 61326-1:2021
BS EN ISO 12100:2010
BS EN 62471:2009
BS EN IEC 63000:2018

EN 61010-1:2010+A1:2019
EN 61326-1:2021
EN ISO 12100:2010
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: Director RA/QA

Date: 06.12.2023
Signed: 