# 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

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: Automated Routine Tissue Processor

Model: EM TP

Order no.: 16 709 204

## 4. *First date of UKCA compliance*

Date: January 11th 2023

## 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 IEC 63000:2018

EN 61010-1:2010+A1:2019
EN 61326-1:2013
EN ISO 12100:2010
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:

Registration no. of the UKCA declaration: UK 245-1
(Leica internal)