

# Declaration of Conformity

The product named below fulfills the requirements of directives and standards listed. In the case of unauthorized modifications to the product or an unintended use this declaration becomes invalid. This declaration of conformity is issued under the sole responsibility of the manufacturer.

**Product Name:**

Centrifuge 5427 R

including components

**Product Type:**

Centrifuge

**Article Number:**

5429 000.XXX

**Relevant Directives / Standards:**

The Medical Devices Regulations 2002 (2002 No. 618):  
EN ISO 13485, EN ISO 18113-1, EN ISO 18113-3, EN ISO 15223-1, EN ISO 14971, EN 61010-2-101, EN 61326-2-6, EN 62366-1

The Supply of Machinery (Safety) Regulations 2008 (2008 No. 1597)  
EN ISO 12100, EN 378-2

The Electrical Equipment (Safety) Regulations 2016 (2016 No. 1101):  
EN 61010-1, EN 61010-2-020

The Electromagnetic Compatibility Regulations 2016 (2016 No. 1091):  
EN 61326-1:2013

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (2012 No. 3032):  
EN IEC 63000

The Waste Electrical and Electronic Equipment Regulations 2013

The Packaging (Essential Requirements) Regulations 2015

The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020

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Certified

ISO 13485  
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ISO 14001  
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**Intended Purpose:**

The Centrifuge 5427 R is a non-automatic centrifuge for separating liquid substance mixtures from the human body and is specifically intended for use as an accessory with an in-vitro diagnostic device in order to facilitate the in-vitro diagnostic device to be used in accordance with its intended use.

**Risk Class:**

General IVD

**Legal Manufacturer:**

Eppendorf SE  
Barkhausenweg 1  
22339 Hamburg  
Germany

**Conformity Assessment Procedure:**

According to PART IV, Regulation 40 (1) of the Medical Devices Regulation 2002 (2002 No. 618)

**Authorized Representative:**

Eppendorf UK Ltd., Eppendorf House, Gateway 1000, Arlington Business Park, Whittle Way Stevenage, SG1 2FP, England

Hamburg, January 10, 2023



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