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 5425 R

including components

Product type:

Centrifuge

Relevant directives / standards:

2017/746/EU:	DIN EN ISO 13485, DIN EN ISO 18113-1, DIN EN ISO 18113-3,DIN EN ISO 14971, DIN EN 61010-2-101, DIN EN 61326-2-6, DIN EN 62366-1
2014/35/EU:	DIN EN 61010-1, DIN EN 61010-2-020
2014/30/EU:	DIN EN 61326-1, DIN EN 55011
2011/65/EU: (incl. (EU) 2015/863)	DIN EN IEC 63000
Further applied standards:	ISO 15223-1, IEC 61010-1 + Cor. + A1 + A1/Cor.1, IEC 61010-2-020, IEC 61010-2-101 UL 61010-1, UL 61010-2-020 CAN/CSA C22.2 No. 61010-1-12, CAN/CSA C22.2 No. 61010-2-020-17 IEC 61326-1, CISPR 11 + A1, 47 CFR FCC part 15 YY/T 0657, GB 4793.1, GB 4793.7, GB 18268.1, YY/T 0466.1, SJ/T 11364, GB/T 26572 ASTM D4169, DIN EN ISO 780

Basic UDI-DI: 04043758-IA-CEN-003-NW

Your local distributor: www.eppendorf.com/contact
Eppendorf SE · Barkhausenweg 1 · 22339 Hamburg · Germany
eppendorf@eppendorf.com

ISO 9001 Certified

ISO 13485 Certified

ISO 14001 Certified

Declaration of Conformity

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Intended Purpose:

The Centrifuge 5425 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:

Class A

Legal Manufacturer:

Eppendorf SE
Barkhausenweg 1
22339 Hamburg
Germany

Single Registration Number (SRN):

DE-MF-000006237

Conformity Assessment Procedure:

Drawing up the technical documentation set out in Annexes II and III of (EU) 2017/746

Hamburg, May 04, 2022

Dr. Wilhelm Plüster
Management Board

Dr. Marlene Jentzsch
Senior Vice President
Division Separation & Instrumentation

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