Declaration of Conformity

The product named below fulfills the requirements of the regulations and directives listed. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product name:
5811 R (and its accessories, which are listed in the related technical file)

Product type:
Multipurpose Centrifuge

Basic UDI-DI:
04043758-IA-CEN-013-P3

From Batch Number or Serial Number:
5831PL000001

The product above complies with all applicable requirements of the regulations and directives listed below:

Intended Purpose:
The Centrifuge 5811 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.

Single Registration Number:
DE-MF-000006237

Risk Class according to Annex VIII (EU) 2017/746:
Risk Class A

Applied standards and technical specifications:

In Vitro Diagnostics Regulation (EU) 2017/746 (IVDR)	EN ISO 18113-1:2024 EN ISO 18113-3:2024 EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021 EN IEC 61010-2-101:2022 + A11:2022 EN IEC 61326-2-6:2021 EN 62366-1:2015 + AC:2015 + A1:2020
Machinery Directive (MD) 2006/42/EC Also conforms with Machinery Regulation (EU) 2023/1230 (incl. the safety requirements of the Low Voltage Directive (LVD) 2014/35/EU and electromagnetic compatibility as per Electromagnetic Compatibility Directive (EMCD) 2014/30/EU)	EN ISO 12100:2010 EN 61010-1:2010 + A1:2019 + A1:2019/AC:2019 EN 378-2:2016 EN 61010-2-020:2017 EN IEC 61326-1:2021
Restriction of Hazardous Substances Directive (RoHS) 2011/65/EU (incl. its supplements Directive(EU) 2015/863 and Directive (EU) 2017/2102)	EN IEC 63000:2018

Legal Manufacturer:

Eppendorf SE
Barkhausenweg 1
22339 Hamburg
Germany

Hamburg, June 10, 2026
The Declaration of Conformity is valid with the date of the signature.

Dr. Christine Luise Munz
Chief Executive Officer

Dr. Philipp Peters
Vice President Quality Management & Regulatory Affairs

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ISO 9001: 2015 certified
ISO 13485: 2016 certified
ISO 14001: 2015 certified

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