

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:

SpinPro 6 R (and its accessories, which are listed in the related technical file)

Product type:

Multipurpose Centrifuge

Basic UDI-DI:

04043758-IA-CEN-012-GV

From Batch Number or Serial Number:

5960PG000067

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

In Vitro Diagnostics Regulation (EU) 2017/746 (IVDR)

Machinery Directive 2006/42/EC

Also conforms with Machinery Regulation (EU) 2023/1230

Radio Equipment Directive (RED) 2014/53/EU (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)

Restriction of Hazardous Substances Directive (RoHS) 2011/65/EU (incl. its supplements Directive (EU) 2015/863 and Directive (EU) 2017/2102)

Legal Manufacturer:

Eppendorf SE
Barkhausenweg 1
22339 Hamburg
Germany

Intended Purpose:

The Centrifuge SpinPro 6 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:

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

EN ISO 12100:2010
EN 61010-1:2010 + A1:2019 + A1:2019/AC:2019
EN 378-2:2016
EN 61010-2-020:2017

EN 300 330 V2.1.1:2017
EN 301 489-1 V2.2.3:2019
EN 301 489-3 V2.3.2:2023
EN 18031-1:2024
EN IEC 61326-1:2021
EN IEC 62311:2020
EN IEC 62368-1:2020 + A11:2020

EN IEC 63000:2018

Hamburg, February 19, 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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