

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

From Batch Number or Serial Number:

5960PG000067

Risk Class:

Risk Class A

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

The Medical Devices Regulations 2002

The Supply of Machinery (Safety) Regulations 2008

The Radio Equipment Regulations 2017 (incl. the safety requirements of The Electrical Equipment (Safety) Regulations 2016 and electromagnetic compatibility as per The Electromagnetic Compatibility Regulations 2016)

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

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.

Applied standards and technical specifications:

EN ISO 18113-1:2011
EN ISO 18113-3:2011
EN ISO 15223-1:2021
EN ISO 14971:2019 + A11:2021
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 62311:2020
EN IEC 62368-1:2020 + A11:2020

EN IEC 63000:2018

Legal Manufacturer:

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Authorized Representative:

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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

Your local distributor: www.eppendorf.com/contact

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ISO 9001:
2015
certified

ISO 13485:
2016
certified

ISO 14001:
2015
certified

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