

EC Declaration of Conformity

in accordance with the EC Machinery Directive 2006/42/EC, annex II, part 1, section A

Product designation	Laboratory centrifuge
Product name	Sigma 1-16
Order number	10045
Manufacturer	Sigma Laborzentrifugen GmbH An der Unteren Söse 50 37520 Osterode Germany
Authorised representative for CE matters	Alexander Hörsting

The product named hereinabove was developed, designed, and manufactured in compliance with the relevant, fundamental safety and health requirements of the listed EC directives and norms.

In the event of modifications that were not authorised by the manufacturer or if the product is used in a manner that is not in line with the intended purpose, this declaration will be rendered void.

Directives	Machinery Directive	2006/42/EC
	Low Voltage Directive	2014/35/EU
	EMC Directive	2014/30/EU
	RoHS Directive	2011/65/EU
	Delegated RoHS Directive	(EU) 2015/863
Norms		EN 61010-2-020:2017 EN IEC 61326-1:2021

Osterode, 2025-11-04



Dr. Michael Sander, Managing Director

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Product designation	Laboratory centrifuge
Product name	Sigma 1-16 IVD
Part numbers	10049
Manufacturer	Sigma Laborzentrifugen GmbH An der Unteren Söse 50 37520 Osterode Germany
Basic UDI as referred to in Part C of Annex VI	426073439IVD01001JQCJ4
Single Registration Number	DE-MF-000009414

As the manufacturer of the unit(s), we assume full responsibility and hereby declare that the product(s) mentioned hereinabove comply with the requirements as set out in the following regulation(s)/directive(s)..

Regulations	Regulation on in vitro diagnostica	(EU) 2017/746
Directives	RoHS Directive	2011/65/EU
	Delegated RoHS Directive	(EU) 2015/863
Risk class in accordance with Annex VIII	class A	

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Dr. Michael Sander, Managing Director