

## 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 4-5KL  
**Order number** 100004, 100005, 100013  
**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 regulations, 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.

<b>Regulations</b>	Implementation Regulation for Regulation (EU) 2024/573 (F-gases Regulation)	(EU) 2024/2729
<b>Directives</b>	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
<b>Norms</b>		EN 61010-2-020:2017
		EN IEC 61010-2-011:2021
		EN IEC 61326-1:2021

Osterode, 2025-11-04



Dr. Michael Sander, Managing Director

## EC Declaration of Conformity

<b>Product designation</b>	Laboratory centrifuge
<b>Product name</b>	Sigma 4-5KL IVD
<b>Part numbers</b>	100006, 100007, 100012
<b>Manufacturer</b>	Sigma Laborzentrifugen GmbH An der Unteren Söse 50 37520 Osterode Germany
<b>Basic UDI as referred to in Part C of Annex VI</b>	426073439IVD01001JQCJ4
<b>Single Registration Number (SRN)</b>	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).

<b>Regulations</b>	Regulation on in vitro diagnostics (EU) 2017/746 Implementation Regulation for Regulation (EU) 2024/573 (F-gases Regulation) (EU) 2024/2729
<b>Directives</b>	RoHS Directive 2011/65/EU Delegated RoHS Directive (EU) 2015/863
<b>Risk class in accordance with Annex VIII</b>	class A

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Dr. Michael Sander, Managing Director