

EC – DECLARATION OF CONFORMITY

The product named hereinafter 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 us or if the product is used in a manner that is not in line with the intended purpose, this declaration will be rendered void.

<i>Product designation:</i>	Laboratory centrifuge	
<i>Product name:</i>	Sigma 1-16K	
<i>Order number:</i>	10046, 10047, 10048	
<i>Regulations:</i>	(EU) 2024/2729	Implementation regulation for regulation (EU) 2024/573 (F-gases regulation)
<i>Directives:</i>	2006/42/EC	Machinery Directive
	2014/35/EU	Low Voltage Directive
	2014/30/EU	EMC Directive
	(EU) 2015/863	RoHS Directive
<i>Normes:</i>	EN 61010-2-020:2017	
	EN IEC 61010-2-011:2021	
	EN IEC 61326-1:2021	

Sigma Laborzentrifugen GmbH

An der Unteren Söse 50
37520 Osterode
Germany

Authorised representative
for CE matters:
Eckhard Tödteberg

Osterode, 2024-12-04



Managing Director

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<i>Product designation:</i>	Laboratory centrifuge
<i>Product name:</i>	Sigma 1-16K IVD
<i>Part number:</i>	10052, 10053, 10054
<i>Basic UDI as referred to in Part C of Annex VI:</i>	426073439IVD01001JQCJ4
<i>Manufacturer:</i>	Sigma Laborzentrifugen GmbH An der Unteren Söse 50 37520 Osterode Germany
<i>Single Registration Number (SRN):</i>	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).

<i>Regulations:</i>	(EU) 2017/746	Regulation on in vitro diagnostica
	(EU) 2024/2729	Implementing Regulation to Regulation (EU) 2024/573 (F-Gas Regulation)
<i>Directives:</i>	(EU) 2015/863	RoHS directive
<i>Risk class in accordance with Annex VIII</i>	Class A	

Osterode, 2024-12-04



Managing Director