EC Declaration of Conformity

Product designation	Laboratory centrifuge
Product name	Sigma 3-18KT IVD
Part numbers	100019; 100021; 100022
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 (SRN)	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
	Implementation Regulation for Regulation (EU) 2024/573 (F-gases Regulation)	(EU) 2024/2729
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 61010-2-011:2021
		EN IEC 61326-1:2021
		EN IEC 61010-2-101:2023

Risk class in accordance with Annex VIII	class A

Osterode, 2026-06-10

Dr. Michael Sander, Managing Director

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 3-18KT
Order number	100014; 100016
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.

Regulations	Implementation Regulation for Regulation (EU) 2024/573 (F-gases Regulation)	(EU) 2024/2729
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 61010-2-011:2021 EN IEC 61326-1:2021

Osterode, 2025-11-04

Dr. Michael Sander, Managing Director