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.

Product name:	Laboratory centrifuge
Product type:	Sigma 3-16KL
Order number:	10360, 10361, 10362, 91027
Directives:	2006/42/EC Machinery Directive 2014/35/EU Low Voltage Directive 2014/30/EU EMC Directive (EU) 2015/863 RoHS Directive
Normes:	EN 61010-2-020:2017 EN 61010-2-011:2017 EN IEC 61000-3-2:2019 EN 61000-3-3:2020 EN 61326-1:2013

Sigma Laborzentrifugen GmbH
An der Unteren Söse 50
37520 Osterode
Germany

Authorised representative
for CE matters:
Eckhard Tödteberg

Osterode, 22/02/2022

General Manager

EC – DECLARATION OF CONFORMITY

Product designation:	Laboratory centrifuge
Product name:	Sigma 3-16KL IVD
Part number:	10363, 10364
Basic UDI as referred to in Part C of Annex VI:	426073439IVD01001JQCJ4
Manufacturer:	Sigma Laborzentrifugen GmbH An der Unteren Söse 50 37520 Osterode Germany
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:	(EU) 2017/746	Regulation on in vitro diagnostica
Directives:	(EU) 2015/863	RoHS directive
Risk class in accordance with Annex VIII	Class A	

Osterode, 02/02/2022

Michael Sander

General Manager