

## **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 name:</i>	Laboratory centrifuge
<i>Product type:</i>	Sigma 1-16K
<i>Order number:</i>	10046, 10047, 10048
<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 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

<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
<i>Directives:</i>	(EU) 2015/863 RoHS directive
<i>Risk class in accordance with Annex VIII</i>	Class A

Osterode, 02/02/2022

*Michael Souder*  
General Manager