

EC – DECLARATION OF CONFORMITY

<i>Product designation:</i>	Laboratory centrifuge
<i>Product name:</i>	Sigma 3-16KL IVD
<i>Part number:</i>	10363, 10364
<i>Basic UDI as referred to in Part C of Annex VI:</i>	—
<i>Manufacturer:</i>	Sigma Laborzentrifugen GmbH An der Unteren Söse 50 37520 Osterode Germany
<i>Single Registration Number (SRN):</i>	—

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, 26/04/2021

Michael Souder
General Manager