

EC – DECLARATION OF CONFORMITY

<i>Product designation:</i>	Laboratory centrifuge
<i>Product name:</i>	Sigma 8KBS
<i>Order numbers:</i>	10635, 10636, 91302
<i>Basic UDI as referred to in Part C of Annex VI:</i>	426073439MD01001KSOHH
<i>Manufacturer:</i>	Sigma Laborzentrifugen GmbH An der Unteren Söse 50 37520 Osterode (Germany) 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).

The product mentioned hereinabove is subject to the conformity assessment procedure as per Regulation (EU) 2017/745 on medical devices, Appendix IX, Chapter I and III (class IIa and class IIb devices), under the supervision of the notified body 0123, TÜV SÜD Product Service GmbH, certificate number G10 012211 0216 rev. 00.

<i>Regulations:</i>	(EU) 2017/745 Regulation on medical devices (EU) 2024/2729 Implementation regulation for regulation (EU) 2024/573 (F-gases regulation)
<i>Directives:</i>	(EU) 2015/863 RoHS directive
<i>Risk class in accordance with Annex VIII:</i>	Class IIa

Osterode, 2024-12-04



Managing Director