

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 2-7 Sigma 2-7 Cyto		
Order number:	10226 10228		
Directives:	2006/42/EC 2014/35/EU 2014/30/EU (EU) 2015/863	Machinery Directive Low Voltage Directive EMC Directive RoHS Directive	
Normes:	EN 61010-2-020:2017 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

for CE matters: Eckhard Tödteberg

Authorised representative

Osterode, 22/02/2022

Michael Sander

General Manager

CE_2-7_2-7Cyto_2022-02-22_en Page 1 / 1



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Product designation:	Laboratory centrifuge	
Product name:	Sigma 2-7 IVD	
Part number:	10227	
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

General Manager

CE_2-7_IVDR_2022-02-02_en Page 1 / 1