CE

greiner BIO-ONE

EU Declaration of Conformity

to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices

Manufacturer:	Greiner Bio-One GmbH Bad Haller Straße 32 4550 Kremsmünster Austria	SRN: AT-MF-000024608
Production Location:	Greiner Bio-One GmbH Bad Haller Straße 32 4550 Kremsmünster Austria	Neomed S.r.l. Via per Ossona, 22 20010 Casorezzo (MI) Italy
Product / Product Group:	ESR Rack (for details please refer to page 2)	
BASIC-UDI-DI (GMN):	refer to page 2	
Classification:	Class A according to Regulation (EU) 2017/746 of the european parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices, Annex VIII Classification Rules - Rule 5	
GMDN Code(s):	refer to page 2	

We herewith declare under our sole responsibility that the products specified above meet the provisions of the above-mentioned Regulation. All supporting documentation is retained under the premises of the manufacturer.

Conformity Assessment procedure acc. to Annex IV of the Regulation (EU) 2017/746.

Standards / common specifications:
Refer to the list of applicable (harmonized) standards and common specifications in the Technical Documentation.

Kremsmünster, 24.03.2023

greiner QM bio-one

Georg Sambs
Quality Manager
Greiner Bio-One Austria

CE

greiner BIO-ONE

PRODUCT GROUP	Product name - detailed product description	Item numbers	GMDN Code	BASIC-UDI-DI (GMN):
ESR Rack (without graduation)	ESR Rack without graduation for 454073	836072	15186	912001757G0000067A7
ESR Rack (with graduation)	ESR Rack with graduation for 729070 / 729090	836075	58170	912001757G0000066A5
ESR Rack (with graduation)	ESR Rack with graduation for 729073 / 729093	836077	58170	912001757G0000066A5