

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

Greiner Bio-One GmbH Manufacturer:

> Bad Haller Straße 32 4550 Kremsmünster

Austria

Production Location:

Greiner Bio-One GmbH Bad Haller Straße 32

4550 Kremsmünster

Austria

Italy

SRN: AT-MF-000024608

Neomed S.r.l.

Via per Ossona, 22

20010 Casorezzo (MI)

Product /

Classification:

ESR Rack

Product Group:

(for details please refer to page 2)

refer to page 2 BASIC-UDI-DI (GMN):

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

Georg Sambs Quality Manager Greiner Bio-One Austria



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