

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 SRN: AT-MF-000024608
Bad Haller Straße 32
4550 Kremsmünster
Austria

Production Greiner Bio-One GmbH Neomed S.r.l.
Location: Bad Haller Straße 32 Via per Ossona, 22
4550 Kremsmünster 20010 Casorezzo (MI)
Austria Italy

Product / ESR Rack
Product Group: (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



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