



EU DECLARATION OF CONFORMITY

According to In vitro diagnostic Regulation (EU) 2017/746



MANUFACTURER: REMI ELEKTROTECHNIK LTD,
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AUTHORISED REPRESENTATIVE: Kingsmead Service B. V.
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SRN NL-AR-000002066

PRODUCT NAME Bench Top Centrifuges

PRODUCT MODEL Neya 5

BASIC UDI-DI 890621264NEYA5FP

PRODUCT CODE 40100202

DEVICE RISK CLASS Class A

REFERENCE: The device is compliant with the following EU harmonization legislation:

- Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices (IVDR)
- Low Voltage Directive (LVD) 2014/35/EU
- Electromagnetic Compatibility Directive (EMC) 2014/30/EU
- RoHS 2 Directive 2011/65/EU, as amended by 2015/863 (Restriction of Hazardous Substances)
- Machinery Directive (MD) 2006/42/EC

CONFORMITY ASSESSMENT PROCEDURE Annex IV, According to Annex II and Annex III of TD

REMI ELEKTROTECHNIK LTD registered as a manufacturer of in vitro diagnostic medical devices, declares under its sole responsibility that: the above mentioned product complies with the product specifications provided by Regulation (EU) 2017/746 of the European Parliament and of the Council related to the in vitro diagnostic medical devices (IVDR).

Signed for and on behalf of: Mr. Bhavin Das, Head QA of REMI ELEKTROTECHNIK LTD

Place: Vasai, India

Date: 14.01.2025

SIGNATURE

