



EU DECLARATION OF CONFORMITY

Manufacturer / name and address: Domel, d.o.o.
Otoki 21
4228 Železniki
Slovenia
Single registration number (SRN): SI-MF-000030074

DOMEL®

We declare that the EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Basic UDI-DI: 383008323CENTRIFUGEWD
Product: Laboratory centrifuge
Trade name: Centric CF 220 IVD
Code: 232.3.005/IVD (230V), 1232.3.005/IVD (120V)
Trade name: Centric MF 220 IVD
Code: 232.3.010/IVD (230V), 1232.3.010/IVD (120V)

Intended purpose:

Centrifuges CENTRIC CF 220 IVD and CENTRIC MF 220 IVD are laboratory centrifuges intended to be used at in vitro diagnostic examinations in laboratories for separating the substances with different specific densities by centrifugal force. They are both in conformity with Regulation (EU) 2017/746 on in vitro diagnostic (IVD) medical devices.

Risk class (IVD regulation): Class A, Rule 5(a) in Annex VIII

The devices that are covered by this declaration are in conformity with the following Regulations, Directives and Standards of Union legislation that provides for the issuing of an EU declaration of conformity:

1. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices
Standards: EN ISO 14971:2019, EN 61010-2-101:2017, EN 61326-2-6:2013, EN 62366-1:2015+A1:2020
2. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits
Standards: EN 61010-1:2010, EN 61010-2-020:2017
3. Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility
Standards: EN 61326-1:2013
4. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, amended by Commission Delegated Directive (EU) 2015/863 and Directive (EU) 2017/2102 of the European Parliament and of the Council
Standards: EN IEC 63000:2018

Common specifications for the devices that are covered by this declaration have not been issued.

Place and date of issue Name and surname with signature of authorized person of the manufacturer

Železniki, 24.11.2022 manager Matjaž Čemažar

Stamp

Version: 2