EU izjava o sukladnosti
EU Declaration of conformity

proizvođača | of the manufacturer

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SRN: DE-MF-000010680

Ovime pod našom odgovornošću izjavljujemo, da je navedeni uređaj:

Vrsta uređaja	**Mala centrifuga**
Naziv	**EBA 200**
Osnovni UDI-DI	**040506740100249W**
GMDN	**47154**
Klasifikacija	**Medicinski uređaj, klasa IIa (Dodatak VIII, Poglavlje III, pravilo 3)**
Prema	**Uredbi (EU) 2017/745 Prilog IX**
Uključeno prijavljeno tijelo	**mdc certifikat medicinskog uređaja GmbH; CE 0483 Kriegerstraße 6; 70191 Stuttgart; Njemačka**

uključujući pribor koji je ocijenjen za sukladnost s uređajem prema popisu pribora u povezanoj tehničkoj dokumentaciji, u skladu je s relevantnim odredbama Uredbe (EU) 2017/745 o medicinskim proizvodima.

Namjena korištenja

Centrifuga **EBA 200 MD** je medicinski proizvod prema uredbi o medicinskim uređajima (EU) 2017/745.
Uređaj služi za razdvajanje pune krvi ili krvnih komponenti ljudskog podrijetla na komponente. Korisnik može postaviti promjenjive fizikalne parametre unutar granica koje je odredio uređaj.

Centrifugu smije koristiti samo stručno osoblje u zatvorenim laboratorijima.

We hereby declare under our responsibility that the designated device:

Type of device	**Small centrifuges**
Name	**EBA 200**
Basic UDI-DI	**040506740100249W**
GMDN	**47154**
Classification	**Medical Device, class IIa (Annex VIII, Chapter III, Rule 3)**
according to	**Regulation (EU) 2017/745 Annex IX**
Involved Notified Body	**mdc medical device certification GmbH; CE 0483 Kriegerstraße 6; 70191 Stuttgart; Germany**

and its accessories, which are listed in the related technical documentation and whose conformity has been assessed together with the device, complies with the relevant provisions of the Regulation (EU) 2017/745 on medical devices.

Intended use

The **EBA 200 (MD)** centrifuge is a medical device according to the Regulation on Medical Devices (EU) 2017/745.
The device is used to separate whole blood or blood components of human origin into its component parts.
The user can set each of the variable physical parameters within the limits set by the device.

The centrifuge may only be used by qualified personnel in closed laboratories.

Uređaj je također u skladu s primjenjivim odredbama sljedećih europskih direktiva i propisa

- 2006/42/EZ „Direktiva o strojevima“
- 2014/30/EU "EMC direktiva"
- 2014/35/EU "Direktiva o niskom naponu"
- 2011/65/EZ "RoHS direktiva"(bez sudjelovanja navedenog tijela)
- (EZ) 1907/2006 REACH direktiva" (bez sudjelovanja navedenog tijela)

Primijenjeni standardi:
Pogledajte popis primijenjenih standarda koji je dio tehničke dokumentacije.

The device also complies to the applicable provisions of the following European directives, ordinances and standards

- 2006/42/EC “Directive on machinery”
- 2014/30/EU “EMC Directive”
- 2014/35/EU „Low Voltage Directive“
- 2011/65/EC “RoHS Directive” (without involvement of a notified body)
- (EC) 1907/2006 „Regulation on REACH“ (without involvement of a notified body)

Standards applied:
See the list of applied standards that forms part of the technical documentation.

Tuttlingen, 25.09.2025

Ralf Ledda
Direktor, Chief Executive Officer

CE 0483

Ova izjava o sukladnosti vrijedi od 25.09.2025 do 25.08.2027.

This declaration of conformity is valid from 25.09.2025 until 25.08.2027