

# 欧共体合格声明

## EU Declaration of conformity

制造商：

of the manufacturer

**Andreas Hettich GmbH • Föhrenstrasse 12 • D-78532 Tuttlingen • Germany**  
**SRN: DE-MF-000010680**

兹在此全责声明，所述设备：

We hereby declare under our responsibility that the designated device:

设备类型 小型离心分离机

Type of device **Small centrifuges**

名称 **EBA 200**

Name **EBA 200**

Basic UDI-DI **040506740100249W**

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GMDN **47154**

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分类 **医疗产品 · IIa 类**  
**(附录 VIII, 第三章, 第 3 条规定)**

Classification **Medical Device, class IIa**  
**(Annex VIII, Chapter III, Rule 3)**

according to **Regulation (EU) 2017/745**  
**Annex IX**

根据 **法规 (EU) 2017/745**  
**附录 IX**

适用的 **mdc 医疗器械认证**  
认证机构 **GmbH ; CE 0483**  
**Kriegerstraße 6; 70191**  
**Stuttgart; Germany**

Involved **mdc medical device certification**

Notified Body **GmbH; CE 0483**  
**Kriegerstraße 6; 70191**  
**Stuttgart; Germany**

包括所属技术文档配件列表所述的、与设备一起进行了合格评估的配件，符合医疗器械法规 (EU) 2017/745 的相关要求。

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.

### 有可能的使用

### Intended use

根据医疗产品法规 (EU) 2017/745，离心分离机 **EBA 200 (MD)** 属于 医疗产品。

The **EBA 200 (MD)** centrifuge is a medical device according to the Regulation on Medical Devices (EU) 2017/745.

设备用于将人体全血或血液成分分离成各对应的成分。

The device is used to separate whole blood or blood components of human origin into its component parts.

用户可以在由设备规定的极限范围内具体设置可改变的物理参数。

The user can set each of the variable physical parameters within the limits set by the device.

仅允许由专业人员在封闭式实验室中使用离心分离机。

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

设备也符合适用的下列欧洲指令和法规的要求

- 2006/42/EC“机器指令”
- 2014/30/EU“电磁兼容性指令”
- 2014/35/EU“低电压指令”
- 2011/65/EC“RoHS 指令”  
(无认证机构参与)
- (EC) 1907/2006“REACH 法规”  
(无认证机构参与)

应用的标准：

参见应用标准列表，它是技术文档的组成部分。

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, 16.10.2024



Klaus-Günter Ebelte  
首席执行官, Chief Executive Officer



本符合性声明有效期为2024年10月16日至2027年8月25日

This declaration of conformity is valid from 16.10.2024 until 25.08.2027