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：

设备类型	**离心机**
名称	**ROTO SILENTA 630 RS**
Basic UDI-DI	**040506740100019J**
GMDN	**15115**
分类	**医疗产品，IIa 类（附录 VIII，第 III 章，第 3 条规定）**
根据	**法规 (EU) 2017/745 附录 IX**
适用的认证机构	**mdc 医疗器械认证 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。

We hereby declare under our responsibility that the designated device:

Type of device	**Centrifuge**
Name	**ROTO SILENTA 630 RS**
Basic UDI-DI	**040506740100019J**
GMDN	**15115**
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.

有可能的使用

本设备属于实验室离心分离机，适用于医疗用途。 其唯一的治疗用途是在血袋系统中对血液进行离心分离。

分离的血液成分由另外一台设备（分离机）移入相应的卫星袋中。

接下来，通过这种方式获取的各个成分将用于输血或者自动输血。

只允许由献血站或者医院的专业人员操作离心分离机。

离心分离机仅允许用于上述用途。

另作他用或者超出此类用途则视为不按规定使用。Andreas Hettich GmbH 公司概不承担由此产生的损失。 按规定使用也包括遵守操作说明中的所有提示和遵守检修及维护保养间

Intended use

This device is a laboratory centrifuge suitable for medical applications. Their exclusive therapeutic purpose is to centrifuge blood in blood bag systems. The separated blood components are transferred by another device (separator) into corresponding satellite bags. The individual components obtained in this way are then used for transfusion or autotransfusion.

The centrifuge is only to be operated by qualified personnel working for blood donation services or hospitals.

The centrifuge is only intended for the uses referred to above. Any other use or use beyond this is considered improper. Andreas Hettich GmbH shall not be liable for any damage arising from this. Intended use also includes the observation of all

隔时间。

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。

instructions in the Operating Manual and compliance with the required inspection and maintenance intervals.

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, 27.11.2024

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

CE 0483

本符合性声明有效期为2024年11月27日至2027年8月25日

This declaration of conformity is valid from 27.11.2024 until 25.08.2027