欧共体合格声明

EU Declaration of conformity

制造商： | of the manufacturer

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SRN: DE-MF-000010680

在没有认证机构参与的情况下，兹在此全责声明，所述设备：

设备类型	小型离心分离机
名称	**EBA 270**
Basic UDI-DI	**040506740100079W**
GMDN	**36465**
分类	**体外诊断，A 类** **（附录 VIII，第 5 条规定）**
根据	**法规 (EU) 2017/746　附录 IX**

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，符合体外诊断医疗器械法规 (EU) 2017/746 的相关要求。

有可能的使用

离心分离机 **EBA 270** 是一种符合体外诊断医疗器械法规 (EU) 2017/746 要求的体外诊断医疗器械。

设备用于离心分离和提炼人类的样本材料，以便进行下一步加工，从而满足诊断需求。 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。

仅允许由专业人员在封闭式实验室中使用离心分离机。 离心分离机仅允许用于上述用途。 按规定使用也包括遵守操作说明中的所有提示和按时执行检修工作及保养工作。

另作他用或者超出此类用途则视为不按规定使用。 Andreas Hettich GmbH & Co. KG 公司概不承担由此产生的损失。

We hereby declare under our responsibility without involvement of a notified body that the designated device:

Type of device	**Small centrifuges**
Name	**EBA 270**
Basic UDI-DI	**040506740100079W**
GMDN	**36465**
Classification	**in vitro diagnostic, class A (Annex VIII, Rule 5)**
according to	**Regulation (EU) 2017/746 Annex IX**

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) 2017/746 on in vitro diagnostic devices.

Intended use

The centrifuge **EBA 270** is an in vitro diagnostic medical device according to the In vitro Diagnostic Medical Devices Regulation (EU) 2017/746.

The device is used for centrifuging and enriching sample material of human origin for subsequent further processing for diagnostic purposes. 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. The centrifuge is only intended for the use referred to above. Intended use also includes observing all instructions in the Operating Manual and compliance with the required inspection and maintenance work.

Any other use or use beyond this is considered improper. Andreas Hettich GmbH & Co. KG shall not be liable for any damage arising from this.

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, 17.10.2023

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

CE

本合格声明的有效期从 至 2023 年 10 月 17 日 至 2025 年 10 月 24 日

This declaration of conformity is valid from 17.10.2023 until 24.10.2025