EU-Konformitätserklärung
EU Declaration of conformity

des Herstellers | of the manufacturer

Andreas Hettich GmbH & Co. KG • Föhrenstrasse 12 • D-78532 Tuttlingen • Germany
SRN: DE-MF-000010680

Hiermit erklären wir in unserer Verantwortung, dass das bezeichnete Gerät:

Geräteart	**Zentrifuge**
Name	**ROTO SILENTA 630 RS**
Basic UDI-DI	**040506740100019J**
GMDN	**15115**
Klassifizierung	**Medizinprodukt, Klasse IIa (Anhang VIII, Kapitel III, Regel 3)**
Gemäß	**Verordnung (EU) 2017/745 Anhang IX**
Mitwirkende Benannte Stelle	**mdc medical device certification GmbH; CE 0483 Kriegerstraße 6; 70191 Stuttgart; Germany**

inklusive des mit dem Gerät konformitätsbewerteten Zubehörs laut Zubehörliste der zugehörigen technischen Dokumentation, den einschlägigen Bestimmungen der Verordnung (EU) 2017/745 über Medizinprodukte entspricht.

Zweckbestimmung

Bei dem vorliegenden Gerät handelt es sich um eine Laborzentrifuge, die für medizinische Anwendungen geeignet ist. Ihre ausschließliche therapeutische Zweckbestimmung besteht darin, Blut in Blutbeutelsystemen zu zentrifugieren. Die separierten Blutkomponenten werden von einem anderen Gerät (Separator) in entsprechende Satellitenbeutel überführt. Die so gewonnenen Einzelkomponenten werden dann für die Transfusion oder Autotransfusion eingesetzt.
Die Zentrifuge darf nur von Fachpersonal in Blutspendediensten oder Krankenhäusern betrieben werden.
Die Zentrifuge ist nur für die oben genannten Verwendungszwecke bestimmt. Eine andere oder darüberhinausgehende Benutzung gilt als nicht bestimmungsgemäß. Für hieraus entstehende Schäden haftet die Firma Andreas Hettich GmbH & Co. KG nicht. Zur bestimmungsgemäßen Verwendung gehört auch die Beachtung aller Hinweise aus der Bedienungsanleitung und die

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.

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 & Co. KG shall not be liable for any damage arising from this. Intended use also includes the observation of all instructions in the Operating Manual and compliance with the required inspection and maintenance intervals.

Einhaltung der Inspektions- und Wartungsintervalle.

Das Gerät entspricht auch den anwendbaren Bestimmungen der folgenden europäischen Richtlinien und Verordnungen

- 2006/42/EG „Maschinenrichtlinie“
- 2014/30/EU „EMV-Richtlinie“
- 2014/35/EU „Niederspannungsrichtlinie“
- 2011/65/EG „RoHS-Richtlinie“
  (ohne Beteiligung einer benannten Stelle)
- (EG) 1907/2006 „REACH Verordnung“
  (ohne Beteiligung einer benannten Stelle)

Angewandte Normen:
Siehe Liste der angewandten Normen, die Teil der technischen Dokumentation ist.

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, 30.10.2023

Klaus-Günter Eberle
Geschäftsführer, Chief Executive Officer

CE 0483

Diese Konformitätserklärung ist gültig von 30.10.2023 bis 25.08.2027

This declaration of conformity is valid from 30.10.2023 until 25.08.2027

Certificate

mdc medical device certification GmbH
certifies that

Andreas Hettich GmbH & Co. KG
Föhrenstraße 12
78532 Tuttlingen
Germany

for the scope

Design, development, manufacturing, distribution and servicing of laboratory centrifuges for IVD applications and general laboratory use, centrifuges for separation of blood components for transfusion purposes and microbiological incubators for IVD applications and general laboratory use

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from	2022-10-25
Valid until	2025-10-24
Registration no.	D1459300003
Report no.	P21-01967-222238
Stuttgart	2022-10-25

Head of Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: DE-MF-000010680)

Andreas Hettich GmbH & Co. KG

Föhrenstraße 12
78532 Tuttlingen
Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils the following requirements:

Annex IX - Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2022-10-25	Registration No.	D1459300004
Valid until:	2027-08-25	Evaluation Report No.	222250

Stuttgart, 2022-10-25

Head of Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Product: Centrifuges for separation of blood components for transfusion purposes and for preparatory diagnostics of transfusion blood

Risk class: IIa

Andreas Hettich GmbH & Co. KG | Postfach 260 | 78503 Tuttlingen | Germany

To our customers

Andreas Hettich GmbH & Co. KG
+49 7461 705-0
info@hettichlab.com
www.hettichlab.com

REACH Compliance

Tuttlingen, den 03. April 2018

Dear Sir or Madam,

We are advising you with this letter, in compliance with the REACH EU Regulation for Chemicals and their safe use (Regulation (EC) No. 1907/2006), that Andreas Hettich GmbH & Co. KG is not an importer or manufacturer of substances or preparations but the company does import products in accordance with REACH. Consequently, the products which we supply you with do not need to be pre-registered or registered.

As part of the supply chain, we have an obligation to ensure that the substances in the products are registered within the specified periods and our customers receive the information they are entitled to in accordance with Art. 33 of the REACH regulation. For this reason, we are in contact with our suppliers with regard to their procedures.

We can confirm the following based on all the responses we have received from our suppliers to date:

- Our suppliers and subsuppliers confirm that they comply with REACH so substances which need to be registered have been registered by each of our upstream suppliers.

- To date, we have not received notification from any of our suppliers about products which contain in excess of 0.1 percent by weight of Substances of Very High Concern (SVHC substances). According to the information currently in our possession, the products we supply to your company consequently do not contain any SVHC substances in accordance with the current list, which is published on the website of the European Chemicals Agency (ECHA), with a concentration in excess of 0.1 percent by weight. Should this status change in any way, we will advise you of this immediately.

We hope you will understand that we are not able to deal with any standard questionnaires on these issues.

Mit freundlichen Grüßen / Best regards,
Andreas Hettich GmbH & Co. KG

i.A.

Christian von der Grün
Head of Regulatory- & Quality Affairs

ALLG000103

Andreas Hettich GmbH & Co. KG | Föhrenstraße 12 | 78532 Tuttlingen | Germany

To our customers

Michael Eberhard

+49 7461 705 1318
Michael.Eberhard@hettichlab.com
www.hettichlab.com

Dear Customer

Tuttlingen, 22.07.2021

RoHS 2011/65 / EU conformity and compliance with the Delegated Directive (EU) 2015/863

We hereby inform you that Andreas Hettich GmbH & Co. KG manufactures and delivers the products of the product groups

- Medical devices according to Directive 93/42/EEC, as well as their accessories and spare parts from July 22nd, 2014
- In-Vitro diagnostic devices according to Directive 98/79/EC, as well as their accessories and spare parts from July 22nd, 2016

conformal to EU Directive 2011/65/EU of the European Parliament and the Council of June 8th, 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II) as well as to the Delegated Directive (EU) 2015/863 of the Commission from March 31, 2015 amending Annex II of Directive 2011/65/EU.

The EC declarations of conformity for these products contain the 2011/65/EC and (EU) 2015/863 as applicable directives. They are part of the technical documentation of every product supplied.

Best regards,
Andreas Hettich GmbH & Co. KG

i.A. Michael Eberhard
Head of Regulatory & Quality Affairs

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Andreas Hettich GmbH & Co. KG

Föhrenstr. 12
78532 Tuttlingen
Germany

has established and applies
a Quality Management System for

Development, production and distribution of laboratory equipment, accessories, spare parts with the associated services.

An audit was performed, Order No. **707111087**.

Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2021-06-10** until **2024-06-09**.

Certificate Registration No.: **12 100 59604 TMS**.

Head of Certification Body
Munich, 2021-05-27

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-01/2019

CERTIFICATE

This is to certify that the company

Andreas Hettich GmbH & Co.KG

Föhrenstraße 12
78532 Tuttlingen
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Design and development, Manufacturing, Distribution and Servicing of laboratory centrifuges for IVD and general laboratory purposes, centrifuges for separation of blood components for transfusion purposes, microbiological incubators for IVD purposes and general laboratory purposes.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	546262 MDSAP16
Certificate unique ID	170777224
Effective date	2022-06-10
Expiry date	2025-06-09
Frankfurt am Main	2022-06-10

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.dqs.de/en/customer-database/ to validate this certificate.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 546262 MDSAP16
Certificate unique ID: 170777224
Effective date: 2022-06-10

Andreas Hettich GmbH & Co.KG

Föhrenstraße 12
78532 Tuttlingen
Germany

Audited site	REPs FEI No.: site scope and country-specific requirements
546262 **Andreas Hettich GmbH & Co.KG** Föhrenstraße 12 78532 Tuttlingen Germany	Design and development, Manufacturing, Distribution and Servicing of laboratory centrifuges for IVD and general laboratory purposes, centrifuges for separation of blood components for transfusion purposes, microbiological incubators for IVD purposes and general laboratory purposes. **-AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F002477**

Annex to certificate
Certificate registration No.: 546262 MDSAP16
Certificate unique ID: 170777224
Effective date: 2022-06-10

Andreas Hettich GmbH & Co.KG

Föhrenstraße 12
78532 Tuttlingen
Germany

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Andreas Hettich GmbH & Co. KG

Föhrenstr. 12
78532 Tuttlingen
Germany

has established and applies
an Environmental Management System for

Development, production and distribution of laboratory equipment, accessories, spare parts with the associated services.

An audit was performed, Order No. **707111087**.

Proof has been furnished that the requirements according to

ISO 14001:2015

are fulfilled.

The certificate is valid from **2021-05-26** until **2024-05-25**.

Certificate Registration No.: **12 104 59604 TMS**.

Head of Certification Body
Munich, 2021-05-27

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-01/2019