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

Christian von der Grün

+49 7461 705 1318
christian.vondergruen@hettichlab.com
www.hettichlab.com

CUSTOMER INFORMATION

TRANSITION PHASE - MDR 2017/745 AND IVDR 2017/746

Tuttlingen, 09.04.2020

Dear valued Customer,

Andreas Hettich GmbH & Co. KG as legal manufacturer is required to comply with EU Medical Device Regulation 2017/745 and EU In-Vitro Diagnostic Medical Device Regulation 2017/746 for the following medical devices / in vitro diagnostic medical devices:

Medical Devices	ROTO SILENTA 630 RS, ROTIXA 500 RS, ROTANTA 460; ROTANTA 460R, ROTANTA 460RC; ROTANTA 460RF
IVD Medical Devices	EBA 200; EBA 200S, EBA 270, EBA 280; EBA 280S, MIKRO 220; MIKRO 220R, UNIVERSAL 320; UNIVERSAL 320R, MIKRO 185, MIKRO 200; MIKRO 200R, ROTOFIX 32A, ROTINA 380; ROTINA 380R, ROTINA 420; ROTINA 420R, HAEMATOKRIT 200; HETTCUBE ff.

We started already our transition phase in the beginning of 2019 and are currently under implementation of the new requirements.

Our current EN ISO 13485:2016 Certificate, MDSAP Certificate and CE-Certificate MDD 93/42/EEC Annex II remains valid until the end of the transition phase for our in vitro diagnostic devices under IVDR 2017/746 until **26.05.2022** and for our medical devices under MDR 2017/745 until **26.05.2024**.

We will publish the successful transition of our product portfolio on our web page as soon as available.

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

i.A.

Digitally signed by Grabazei Alexandru
Date: 2021.05.08 09:50:43 GMT+02:00
Reason: MoldSign Signature
Location: Moldova

Christian von der Grün
Head of Regulatory & Quality Affairs

ALLG000104

Digitally signed by Grabazei Alexandru
Date: 2021.02.09 14:52:58 EET
Reason: MoldSign Signature
Location: Moldova

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

EG-Konformitätserklärung
EC Declaration of conformity
Déclaration de conformité CE
Dichiarazione di conformità CE

des Herstellers / of the manufacturer / du fabricant / del costruttore

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

Hiermit erklären wir in alleiniger Verantwortung, dass das bezeichnete Gerät, inklusive dem mit dem Gerät konformitätsbewertetem Zubehör laut Zubehörliste der technischen Dokumentation dieses Geräts, der Richtlinie für Medizinprodukte 93/42/EWG entspricht.

We hereby declare under our sole responsibility that the designated device and its accessories, which are listed in the technical documentation for this device and whose conformity has been assessed together with the device, conform to the Medical Device Directive – Council Directive 93/42/EEC.

Par la présente, nous déclarons sous notre seule responsabilité que l'appareil désigné, incluant ses accessoires attestés conformes d'après la liste des accessoires de la documentation technique du dit-appareil, répond à la directive 93/42/CEE sur les produits médicaux.

Si dichiara nella nostra sola responsabilità, che l'apparecchiatura indicata, comprensiva dei conformi accessori come da elenco della documentazione tecnica di questa apparecchiatura, risponde alle direttive per prodotti medicali 93/42/CEE.

Geräteart / Type of device / Type d'appareil / Tipo di apparecchio:

Laborzentrifuge / Laboratory centrifuge / Centrifugeuse de laboratoire / Centrifuga di laboratorio

Typenbezeichnung / Type designation / Désignation du type / Denominazione del tipo:

ROTO SILENTA 630 RS

Das Konformitätsbewertungsverfahren wurde nach Anhang II der Richtlinie 93/42/EWG unter Mitwirkung der nachfolgenden benannten Stelle durchgeführt:

The conformity evaluation process was performed in accordance with appendix II of Directive 93/42/EEC involving the following notified bodies:

La procédure d'évaluation de la conformité a été réalisée conformément à l'annexe II de la directive 93/42/CEE avec le concours de la société désignée ci-après:

La procedura di valutazione di conformità è stata eseguita conformemente da appendice II delle direttive 93/42/CEE con il concorso dei seguenti collaboratori:

mdc medical device certification GmbH – Notified Body CE 0483
tel: +49 (0)711 253597 0
fax: +49 (0)711 258597 10
e-mail: mdc@mdc-ce.de
website: www.mdc-ce.de
mail: Kriegerstraße 6, D-70191 Stuttgart; Germany

Folgende weitere europäische Richtlinien und Verordnungen wurden angewandt:

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

Angewandte Normen:

Gemäß Liste der angewandten Normen, die Teil der Produktakte ist.

The following additional European directives and ordinances have been applied:

- Machinery Directive 2006/42/EU
- EMC directive 2014/30/EU
- Low voltage directive 2014/35/EU
- RoHS II Directive 2011/65/EU (without involvement of a notified body)
- Ordinance (EC) No. 1907/2006 (REACH) (without involvement of a notified body)

Applied standards:

According to the list of applied standards, which is part of the product file.

Les autres directives et normes européennes suivantes ont été appliquées:

- Directive 2006/42/UE relative aux machines
- Directive CEM 2014/30/UE
- Directive basse tension 2014/35/UE
- Directive RoHS II 2011/65/UE (sans participation d'un organisme désigné)
- Directive (CE) no. 1907/2006 (REACH) (sans participation d'un organisme désigné)

Normes appliquées:

Conformément à la liste des normes appliquées relatives aux cycles du produit.

Sono state applicate le seguenti direttive e regolamenti europei:

- Direttive per macchine 2006/42/EU
- Direttive per compatibilità elettromagnetica 2014/30/EU
- Direttive per basse tensioni 2014/35/EU
- RoHS II direttive 2011/65/EU (senza concorso di un citato collaboratore)
- Regolamento (CE) n. 1907/2006 (REACH) (senza concorso di un citato collaboratore)

Norme applicate:

Conformemente alla lista delle norme applicate, che sono parte degli atti del prodotto.

Letzte Gültigkeit dieser Erklärung:

Entsprechend dem letzten Gültigkeitsdatum der zum Zeitpunkt der Ausstellung dieser Erklärung gültigen EG-Konformitätsbescheinigung, die durch die o.g. benannte Stelle nach Anhang II der Richtlinie 93/42/EWG ausgestellt wurde: 2024-05-26

Last validity of this declaration:

In accordance with the last date of validity of the EC certificate of conformity as issued by the above-mentioned notified body in accordance with appendix II of Directive 93/42/EEC which was valid at the time of the issuance of this declaration: 2024-05-26

Dernière validité de cette déclaration:

Conformément à la dernière date de validité de l'attestation de conformité CE valide au moment où elle a été établie par la société mentionnée ci-dessus conformément à l'annexe II de la directive 93/42/CEE : 2024-05-26

Ultima validità di questa dichiarazione:

Conformemente all'ultima data di validità del certificato di conformità CE valido al momento della pubblicazione di questa dichiarazione, che è stata esposta tramite l'ufficio sopra citato come da appendice II delle direttive 93/42/CEE: 2024-05-26

Tuttlingen, 2020-04-01

Klaus-Günter Eberle

Geschäftsführer, Manager,
Directeur, Gerente

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

TÜV SÜD 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 **2020-03-02** until **2021-06-09**.

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

Product Compliance Management
Munich, 2020-03-02

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

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

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 certificate and applicable country-specific requirements:
Design and development, manufacturing, distribution and servicing of laboratory centrifuges, centrifuges for separation of blood components for transfusion purposes and microbiological incubators.
-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 (MDSAP Audit Model Edition 2)

including country-specific requirements as shown in the scope
(full references are listed in the annex)

Certificate registration no.	228146 MDSAP16
Certificate unique ID	170723858
Effective date	2019-07-11
Expiry date	2022-07-10
Frankfurt am Main	2019-07-11

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
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.mydqs.com/en/customers/customer-database.html to validate this certificate.

413.01.001 Version 2.0

Annex to certificate
Certificate registration No.: 228146 MDSAP16
Certificate unique ID: 170723858
Effective date: 2019-07-11

Andreas Hettich GmbH & Co.KG

Föhrenstraße 12
78532 Tuttlingen
Germany

Audited site

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

DUNS No., site scope and country-specific requirements

Design and development, manufacturing, distribution and servicing of laboratory centrifuges, centrifuges for separation of blood components for transfusion purposes and microbiological incubators.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)
DUNS No.: 316403245

This annex is only valid in connection with the above-mentioned certificate.

Annex to certificate
Certificate registration No.: 228146 MDSAP16
Certificate unique ID: 170723858
Effective date: 2019-07-11

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. 16/2013 RDC ANVISA n. 23/2012 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

This annex is only valid in connection with the above-mentioned certificate.