Letter of information

Transition period MDR

Dear Sir or Madam,

The purpose of this letter is to draw your attention to EU Regulation 2023/607, which entered into force on 15 March 2023. This Regulation deals with amendments to Regulations (EU) 2017/745 and (EU) 2017/746 regarding transitional provisions for certain medical devices and in vitro diagnostic medical devices.

Pursuant to Art. 1(2) (EU 2023/607) in conjunction with Art. 1, para 3 (EU 2023/607), a manufacturer is authorised to continue to place on the market or put into service non-implantable Class IIb devices and Class IIa devices which comply with Directive 93/42/EEC (MDD) after the expiry of the period specified in the certificate until 31 December 2028, provided that the following conditions are met:

- The manufacturer has a certificate under 93/42/EEC that was issued after 25 May 2017, was still valid on 26 May 2021, and was not subsequently withdrawn by the notified body;
- The product continues to comply with Directive 93/42/EEC;
  (Art. 1, Para. 3c, S.a, EU 2023/607)
- There are no significant changes to the design or intended purpose;
  (Art. 1, para 3c, S.b, EU 2023/607)
- The device does not present an unacceptable risk to the health or safety of the patient, user, third parties or public health ;
  (Art. 1, para. 3c, S.c, EU 2023/607)
- The manufacturer has established a quality management system in accordance with Art. 10, para. 9, MDR by 26 May 2024 at the latest ;
  (Art. 1, para 3c, S.d, EU 2023/607)
- The manufacturer has submitted a formal application for conformity assessment for the products concerned to a notified body by 26 May 2024 and the two parties have signed a written agreement to this effect by 26 September 2024 at the latest.
  (Art. 1, para. 3c, S.e, EU 2023/607)

Our MDD certificate is valid from 21 May 2019 until 05 May 2024. There are no plans to change the intended use, nor do our products present an inacceptable risk. In addition, we have established the required quality management system in the company and have a conformity assessment agreement with a Notified Body. A certificate from out Notified Body is attached.

By meeting all of the above requirements, EEG Medical (former Heyer Benelux), is authorised to continue to place on the marker or put into service medical devices they comply with Directive 93/42/EEC (MDD).

However, we already comply with current requirements such as port-market surveillance and vigilance.
Of course, we will keep an eye on any changes to the regulatory requirements so that we can continue to provide compliant medical devices to the market.

Yours sincerely,
Joren Petrus – PRRC

03/09/2024

TÜVNORD

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TÜV®

Our / Your Reference	Contact	Direct Dial	Date
Reg. No. Under MDD: 44232160752 B ed. 4	TÜV NORD CERT Medical medical@tuev-nord.de	Tel.: -2236	3 September 2024

Confirmation

Certification of a Quality Management System according to (EU) 2017/745 (MDR) Ann. IX, I & III

TÜV NORD CERT GmbH as a notified body for medical devices under the Medical Device Regulation (EU)2017/745 herewith confirms that the company **EEG Medical** (former Heyer Benelux NV) has signed the offer for a conformity procedure under (EU) 2017/745 (MDR) on 26.04.2024.

TÜV NORD CERT GmbH has received the MDR application review documents on 23.05.2024. The application is currently under review.

Due to the complexity of the conformity assessment procedure and the unforeseeable final decision concerning the certification neither the issuance itself nor the exact date of issuance of a certificate under the MDR can be predicted at this point.

Best regards,

TÜVNORD Digital unterschrieben von Jung Klaus Datum: 2024.09.03 14:59:24 +02'00'

TIC Manager MDR

Medical Devices International
TÜV NORD CERT GmbH

TÜVNORD i. V. Digital unterschrieben von Schmidt Caroline Datum: 2024.09.03 15:08:13 +02'00'

Deputy Head Project Management

Medical Devices International
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Unser/Ihr Zeichen	Ansprechpartner/in	Durchwahl	Datum
ZA / Reg. No.: 35380017 / 44 232 161081_Best. 001_B Ed. 3_A1 Ed. 4 Date of notification: 2024-07-19 Confirmation No.: 003	TÜV NORD CERT Medical medical@tuev-nord.de	Tel/Phone: -2236 PM-Team	3. September 2024

Schriftliche Bestätigung zur Korrektur oder Ergänzung von Informationen über gültige Bescheinigungen nach Richtlinie 93/42/EWG unter Berücksichtigung der Bestimmungen der Verordnung (EU) 2017/745, Artikel 120.

Written confirmation correcting or complementing information on valid certificates according to Directive 93/42/EEC taking into account the provisions of Regulation (EU) 2017/745, Article 120

TÜV NORD CERT GmbH, Benannte Stelle für Medizinprodukte, Kennnummer 0044.
TÜV NORD CERT GmbH, Notified Body for medical devices, identification number 0044

Gemäß den Festlegungen in Verordnung (EU) 2017/745, Artikel 120, dürfen noch gültige, unter der Richtlinie 93/42/EWG ausgestellte Bescheinigungen nicht mehr geändert werden. Dieses Schreiben bestätigt Korrekturen oder Ergänzungen von Informationen an nachfolgender, gültiger Bescheinigung.

In accordance with the provisions of Regulation (EU) 2017/745, Article 120, certificates issued under Directive 93/42/EEC that are still valid may no longer be changed. This letter confirms correcting or complementing information of the following valid certificate.

Hersteller / *Manufacturer*

EEG Medical

Lichtenberglaan 2087

3800 Sint-Truident

Belgium

Vorher/*Former*

Heyer Benelux NV

Lichtenberglaan 2087

3800 Sint-Truident

Belgium

Konformitätsbewertungsverfahren / *Conformity assessment procedure*

93/42/EWG Anhang II ohne (4) / *93/42/EEC Annex II without (4)*

Reg. Nr. / *Reg. No.*

44 232 161081

Bericht Nr. / *Report No.*

35380017

Ausstellungsdatum / *Date of issue*	Gültig ab / *Valid from*	Gültig bis / *Valid until*	Edition / *Edition*
2021-05-10	2021-05-10	2024-05-26	3
2023-11-03	2022-10-20	2024-05-26	Korrektur 001 / *Correction 001*
2024-09-03	2024-09-03	--	Korrektur 003 / Correction 003

Änderungsgrund / *Reason of change*

Änderung der Firmierung / *Change of company name*

Änderung / *Change*

EEG Medical

Lichtenberglaan 2087

3800 Sint-Truident

Belgium

Bestätigter Geltungsbereich / *Confirmed scope*

Design, installation, testing and maintenance of medical gas pipeline systems, vacuum networks and supply systems for 'on site' production of air and vacuum.
+ Distribution of medical devices (medical supply units, OR and examination lights, Digital OR, SOT, patient lifts)
+ Installation and maintenance of medical devices and accessories (medical supply units, OR and examination lights, digital OR, patient lifts)

Soweit zutreffend, werden Änderungen des Geltungsbereichs von Bescheinigungen, gemäß den Übergangsvorschriften nach § 96 MPDG, an das "Deutsche Medizinprodukte-Informations- und Datenbanksystem" (DMIDS) gemeldet.

Where applicable, changes to the scope of certificates are reported to the "German Medical Devices Information and Database System" (DMIDS), in accordance with the transitional provisions under Section 96 of the MPDG.

TÜVNORD

Digital unterschrieben
von Jung Klaus
Datum: 2024.09.03
10:43:01 +02'00'

TÜV NORD CERT GmbH
Zertifizierungsstelle für Medizinprodukte
Certification Body for Medical Devices

EG-Zertifikat / *EC-Certificate*

gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Heyer Benelux Medical Technology
Nijverheidslaan 5120
3800 Sint-Truiden
Belgium

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Medical gas distribution and vacuum networks and accessories (Class IIa and IIb Devices)

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 44 232 160752
Bericht Nr. / *Report No.* 3524 4334

Gültigkeit / *Validity*
von / *from* 2019-05-21
bis / *until* 2024-05-05
Edition 4

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-05-21

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16