Caretechion GmbH Niederrheinstraße 71 , 40474 Düsseldorf

CARETECHION

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# European authorized representative Declaration

Caretechion GmbH
Niederrheinstr. 71,
40474 Düsseldorf, Germany
as the EU Authorized Representative for

Manufacturer:
Wujiang City Cloud & Dragon Medical Device Co., Ltd.
West of Building FS-02, No.807 Ganquan West Road, Wujiang Economic Development Zone, Suzhou, Jiangsu 215200, China.

Caretechion GmbH will assume the duties of a European authorized representative and fulfill our obligation to monitor this product entrance of the EU market, into the German DIMDI database according to The Act on Medical Devices (Gesetz überMedizinprodukte - MPG) of Germany, and confirms the submission of the notification of the medical devices

Product name: Magnetic Ball Plasters
Registration Number: **DE/CA20/00193463**

Under Regulation (EU) 2017/745 for medical devices, Manufacturer, Wujiang City Cloud & Dragon Medical Device Co., Ltd., must be responsible for the quality of the products, the legal distribution of the products, and any other problems caused by the quality of the products.
The manufacturer, Wujiang City Cloud & Dragon Medical Device Co., Ltd., has the obligation to comply with the requirements of EU Authorized Representative, Caretechion GmbH, and comply with relevant EU regulations, before the exportation to EU and any sale behaviors in EU, and this manufacturer's relevant importers also have the obligation to send EU Authorized Representative, Caretechion GmbH, the sales list in time.
The remaining terms and agreements are in accordance with the European authorized representative Agreement (NO. YL/2023-001).

Caution: This declaration will automatically be invalid if the upon medical device is written off/wiped out in the EU by the local competent authority or the termination of the EU Authorized Representative Agreement with Catetechion GmbH.

Caretechion GmbH
Niederrheinstr. 71, 40474 Duesseldorf, Germany
Tel:+49 211 3003 6618 Fax:-49 211 3003 6619
DIMDI Code: DE/0000048026
E-mail: info@caretechion.de

wangjian

Caretechion GmbH Date : May 18, 2023 Place: Dusseldorf, Germany

# Allgemeine Anzeigepflicht gemäß Übergangsvorschrift nach §§ 96 und 96a MPDG mit Verweis auf § 25 MPG sowie Anzeige der verantwortliche Person nach Artikel 15 MDR (PRRC)
# General obligation to notify pursuant to transitional regulations §§ 96 and 96a MPDG with reference to § 25 MPG and notification for the Person Responsible for Regulatory Compliance (PRRC) according to article 15 MDR

**Formblatt für Medizinprodukte**
**Form for Medical Devices**

| **Zuständige Behörde / Competent authority** | | | |
|---|---|---|---|
| | Code<br>**DE/CA20** | | |
| | Bezeichnung / Name<br>**Bezirksregierung Düsseldorf, Dezernat 24** | | |
| | Staat / State<br>**Deutschland** | | Land / Federal state<br>**Nordrhein-Westfalen** |
| | Ort / City<br>**Düsseldorf** | | Postleitzahl / Postal code<br>**40474** |
| | Straße, Haus-Nr. / Street, house no.<br>**Cecilienallee 2** | | |
| | Telefon / Phone<br>**+49-211-4750** | | Telefax / Fax<br>**+49-211-4752671** |
| | E-Mail / E-mail<br>**dez24.mpg@brd.nrw.de** | | |

| **Anzeige / Notification** | | | |
|---|---|---|---|
| | Registrierdatum bei der zuständigen Behörde<br>Registration date at competent authority<br>**17.05.2023** | | Registriernummer / Registration number<br>**DE/CA20/00193464** |
| | Rechtsgrundlage / legal basis<br>☐ Medizinprodukte (93/42/EWG bzw. 90/385/EWG) / German Medical Device Act (93/42/EWG or 90/385/EWG)<br>☐ Artikel 120(3) Verordnung (EU) 2017/745 (Legacy Device) / Article 120(3) Regulation (EU) 2017/745 (Legacy Device)<br>☒ Verordnung (EU) 2017/745 (MDR) / Regulation (EU) 2017/745 (MDR) | | |
| | Typ der Anzeige / Notification type<br>☒ Erstanzeige / Initial notification<br>☐ Änderungsanzeige / Notification of change<br>☐ Widerrufsanzeige / Notification of withdrawal | | |
| | Frühere Registriernummer bei Änderungs- und Widerrufsanzeige<br>Previous registration number if notification has been changed or withdrawn | | |
| | Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG<br>☐ Hersteller / Manufacturer<br>☒ Bevollmächtigter / Authorised Representative<br>☐ Einführer / Importer<br>☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG / Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG<br>☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV<br>Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV<br>☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG<br>Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG | | |

| **Anzeigender / Reporting organisation (person)** | | | |
|---|---|---|---|
| | Code<br>**DE/0000048026** | | |
| | Bezeichnung / Name<br>**Caretechion GmbH** | | |
| | Staat / State<br>**Deutschland** | | Land / Federal state<br>**Nordrhein-Westfalen** |
| | Ort / City<br>**Düsseldorf** | | Postleitzahl / Postal code<br>**40474** |
| | Straße, Haus-Nr. / Street, house no.<br>**Niederrheinstraße 71** | | |
| | Telefon / Phone<br>**+49 211 300 366 18** | | Telefax / Fax |
| | E-Mail / E-mail<br>**jian.wang@caretechion.de** | | |

| Hersteller / Manufacturer | | | |
|---|---|---|---|
| | Bezeichnung / Name<br>**Wujiang City Cloud & Dragon Medical Device Co., Ltd.** | | |
| | Staat / State<br>**CN** | | |
| | Ort / City<br>**Suzhou** | | Postleitzahl / Postal code<br>**215200** |
| | Straße, Haus-Nr. / Street, house no.<br>**Ganquan West Road No.807. FS-02** | | |
| | Telefon / Phone<br>**0086-512-63242329** | | Telefax / Fax<br>**0086-512-63242329** |
| | E-Mail / E-mail<br>**info@clouddragon.com** | | |

| Verantworliche Person für die Einhaltung der regulatorischen Vorschriften gemäß Artikel 15 MDR (PRRC)<br>Person Responsible for Regulatory Compliance according to article 15 MDR (PRRC) | | | |
|---|---|---|---|
| | Bezeichnung / Name<br>**Jian Wang** | | |
| | Staat / State<br>**Deutschland** | | Land / Federal state<br>**Nordrhein-Westfalen** |
| | Ort / City<br>**Düsseldorf** | | Postleitzahl / Postal code<br>**40474** |
| | Straße, Haus-Nr. / Street, house no.<br>**Niederrheinstraße 71** | | |
| | Telefon / Phone<br>**+49 211 300 366 18** | | Telefax / Fax |
| | E-Mail / E-mail<br>**jian.wang@caretechion.de** | | |

| Vertreter / Deputy (optional) | | | |
|---|---|---|---|
| | Bezeichnung / Name | | |
| | Telefon / Phone | | Telefax / Fax |
| | E-Mail / E-mail | | |
| | ☐ Erstanzeige / Initial notification<br>☒ Änderungsanzeige / Notification of change | | |

| **Medizinprodukt / Medical device** | |
|---|---|
| | Klasse / Class<br>☒ I<br>☐ I - steril / sterile<br>☐ I - mit Messfunktion / with measuring function<br>☐ I - steril und mit Messfunktion / sterile and with measuring function<br>☐ I - Wiederverwendbare chirurgische Instrumente / Reusable surgical instruments<br>☐ I - Wiederverwendbare chirurgische Instrumente und steril / Reusable surgical instruments and sterile<br>☐ I - Wiederverwendbare chirurgische Instrumente mit Messfunktion / Reusable surgical instruments with measuring function<br>☐ I - Wiederverwendbare chirurgische Instrumente mit Messfunktion und steril / Reusable surgical instruments with measuring function and sterile<br>☐ IIa<br>☐ IIb<br>☐ III<br>☐ III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012<br>manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012<br>☐ Aktives implantierbares Medizinprodukt / Active implantable medical device<br>☐ Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012<br>Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012 |
| | App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no |
| | Nummer(n) der Bescheinigung(en) / Certificate number(s) |
| | Handelsname des Produktes / Trade name of the device |
| | Produktbezeichnung / Name of device<br>**Auricular Point Sticker** |
| | Nomenklaturcode / Nomenclature code<br>**11-374** |
| | Nomenklaturbezeichnung / Nomenclature term<br>**Ohrlochstechinstrument** |
| | Kategoriecode / Category code<br>**10** |
| | Kategorie / Category<br>**Produkte zum Einmalgebrauch** |
| | Kurzbeschreibung deutsch / German short description |

| | |
|---|---|
| | Kurzbeschreibung englisch / English short description<br>**Auricular Point Sticker consists of spheres and tape. Non-sterile provision, single use. The spherical body is made of Gold/silver coated magnetic steel ball or crystal/pearl material, and the tape is made of 3M1533 tape or**<br>**transparent film tape. Stick to the ear points of the human body for external stimulation.**<br>**Non-invasive.** |

| **Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)** | |
|---|---|
| | ☐ Semikritische Medizinprodukte / Semicritical medical devices<br>☐ Gruppe A / Group A<br>☐ Gruppe B / Group B |
| | ☐ Kritische Medizinprodukte / Critical medical devices<br>☐ Gruppe A / Group A<br>☐ Gruppe B / Group B<br>☐ Gruppe C / Group C<br>Nummer der Bescheinigung / Certificate number |
| | Sterilisationsverfahren / Sterilisation procedures<br>☐ Dampfsterilisation / Steam sterilisation<br>☐ Gassterilisation / Gas sterilisation<br>☐ Strahlensterilisation / Radiation sterilisation<br>☐ andere / others<br>Angewandtes Verfahren / Applied procedure |

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Düsseldorf**

Datum
Date **2023-05-17**

Name **Jian Wang**

Unterschrift
Signature

File Name: Declaration of conformity

File No: TCF-C-03

# EC Declaration of Conformity

*Manufacturer:*
Wujiang City Cloud & Dragon Medical Device Co., Ltd.
West of Building FS-02, No.807 Ganquan West Road, Wujiang Economic Development Zone, Suzhou, Jiangsu 215200, China.
Tel: 0512-63242329 Fax: 0512-63242329

*whose single Authorized Representative:*
Caretechion GmbH
Niederrheinstr. 71
40474 Düsseldorf, Germany
DIMDI Code: DE/0000048026
Tel: +49 211 3003 6618 Fax: +49 211 3003 6619
Email: info@caretechion.com

We, the manufacturer, herewith declare that the products

**Auricular Point Sticker**
***UMDNS-Code: 11374***
***UDI-DI-Code:***

Intended use:
Stick to the ear points of the human body for external stimulation. Non-invasive.
Product specifications: 20PCS, 100PCS, 121PCS, 200PCS, 1210PCS.

Meet the provisions of MDR 2017/745 EU which apply to them.

The medical device has been assigned to class I according to Annex VIII of the MDR 2017/745 EU.

CE

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The product concerned has been manufactured under a quality management system according to Annex IX of MDR 2017/745 EU.

Following the procedure relating to the EC Declaration of Conformity set out in Annex IV of MDR 2017/745 EU.

Applied harmonised standards, national standards or other normative documents:
EN ISO 20417-2021. EN ISO 10993-1: 2020. EN ISO 10993-5: 2009. EN ISO 10993-10: 2013. EN ISO 14971: 2019. EN 62366-1:2015. EN ISO 15223-1:2021.

The above mentioned declaration of conformity is exclusively under the responsibility of

**Wujiang City Cloud & Dragon Medical Device Co., Ltd.**
**West of Building FS-02, No.807 Ganquan West Road, Wujiang Economic Development Zone, Suzhou, Jiangsu 215200, China**

Wujiang China 2023-03-28
Place , date

GM: 陈悦婷
Legally binding signature, Function