

# EC Certificate of Conformity

## The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH  
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company:

**Shenzhen Unicare Electronic Co., Ltd.  
3D, Building 4, Tian-an Industrial Zone,  
Nanyou, Shenzhen  
China**

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

## Annex II without section 4

This certification is subject to surveillance by MEDCERT.

**Effective date: 2020-05-27**

**Expiry date: 2023-04-15**

Report No.: 6409PS11F

Process No.: QS – 6409

Certificate No.: 6409GB410200527

Hamburg, 2020-05-27

MEDCERT Certification Body  
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
ZLG-BS-237.10.15

## Appendix of EC Certificate of Conformity

Process No.: QS – 6409  
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### List of products / product categories included in the scope of certificate

- **Patient monitors**
- **Fetal monitors**
- **Fetal dopplers**

– End of list –

This appendix is integral part of the above-referenced certificate.  
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To whom it may concern

DNV MEDCERT GmbH  
Pilatuspool 2  
20355 Hamburg  
Germany

Tel: +49 40 2263325-0  
E-mail: Medcert-Info@dnv.com

**Date:** 2023-08-08  
**Our reference:** QS-6409

**Notified Body Confirmation Letter**  
**Certification No: 6409GB454230808**

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando<sup>1</sup>, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer.

Shenzhen Unicare Electronic Co., Ltd.  
Room 1703, 17th floor, Fifth Block, Seg New City Plaza,  
Longgang, Shenzhen  
PR China  
SRN<sup>2</sup>: CN-MF-000032694

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

<sup>1</sup> Nando (New Approach Notified and Designated Organisations) Information System, <https://ec.europa.eu/growth/tools-databases/nando/>.

<sup>2</sup> Single registration number (SRN) according to Article 31 (2) of MDR.

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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding well established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa devices, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

For DNV MEDCERT GmbH



Monika Hamann  
Customer Service Manager

Appendix (see following pages):

- Table 1 and Table 2
- Revision history



**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|--|--|
| Vital signs monitoring instruments                  | Class IIb excluding Class IIb implantable non-WET   | N/A  | Certificate<br>6409GB410200527<br>NB 0482  |
| Obstetrics and Gynaecology instruments              | Class IIa   | N/A  | Certificate<br>6409GB410200527<br>NB 0482  |

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|--|--|
| None  | None  | None   | None   |

**Confirmation Letter Revision History:**

| Date       | NB internal reference traceable to each version of the letter | Action        |
|------------|---|---------------|
| 2023-08-08 | 6409GB454230808   | Initial issue |