



金成锐医疗

Shenzhen JCR Medical Technology Limited Company

Add.: 101, Building 1, Plant B, No.1, Tianfu Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen, Guangdong, China(518132)

EC DECLARATION OF CONFORMITY

The following EC declaration of conformity exemplifies the required content according to Directive 93/42/EEC.

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: Shenzhen JCR Medical Technology Limited Company
101, Building 1, Plant B, No.1, Tianfu Road, Tianliao Community,
Yutang Street, Guangming District, 518132 Shenzhen, Guangdong,
PEOPLE'S REPUBLIC OF CHINA

We declare under our sole responsibility that

| Productname: | Model | GMDN | UMDN |
|--------------------------------|---|-------|-------|
| Disposable Pressure Transducer | JIBPT-01-YP, (TNC-IBPT-AG) JIBPT-01-UT, (TNC-IBPT-UT) JIBPT-01-BD, (TNC-IBPT-BD) JIBPT-01-EDW, (TNC-IBPT-EW) JIBPT-01-MD, (TNC-IBPT-MXT) JIBPT-01-BL, (TNC-IBPT-BB) JIBPT-01-PVB, (TNC-IBPT-PVB) JIBPT-01-USB, JIBPT-01-MR, (TNC-IBPT-MIR) JIBPT-E-01-YP, JIBPT-E-01-UT, JIBPT-E-01-BD, JIBPT-E-01-EDW, JIBPT-E-01-MD; JIBPT-E-01-BL, JIBPT-E-01-PVB, JIBPT-E-01-USB, JIBPT-E-01-MR. | 35927 | 13114 |

of class: /

Class IIb

according to annex IX of directive 93/42/EEC

Doc.: DOC-01

ver.: A2

date: Nov. 20, 2021



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meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: /

Directive 93/42/EEC Annex II, excluding Section 4

Registration No.:

HD 60147227 0001

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Shenzhen, 2024.5.22.
Place, date /

Guoshuhong
Name and function

Product Intended Use:

Disposable Pressure Transducer is used in Medical unit to monitor various pressure such as patient's arterial Pressure venous , central venous pressure, Pulmonary arterial pressure and left coronary pressure. it is a single use product. it can be used with various kinds of invasive blood pressure. This product is only for use of Experienced medical staff and the guidance to directly or in their use.

The principle, function and structure of the product :

After sterilization, one end of the Disposable Pressure Transducer is connected to patient's blood vessel or pressure cavity, the other end is connected to monitor using a disposable cable, through the microcomputer electric wheatstone bridge of the pressure chip, patient's blood pressure or other cavity pressure is converted to electrical signals when the liquid medicine flows through the sensor, and the monitor conducts signal conditioning so as to monitor the pressure in real time.

This product is only for use of Experienced medical staff and the guidance to directly or in their use.