**Business Stream Products**
Certification Department

TÜVRheinland®
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Shenzhen JCR Medical Technology
Limited Company
101, Building 1, Plant B, No.1,
Tianfu Road, Tianliao Community,
Yutang Street, Guangming District,
Shenzhen
518132 Guangdong
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date December 14, 2021

**Application for** : **QMS**
Certificate No. : HD 60147227 0001
Requirement : Richtlinie 93/42/EWG
Confirmation letter ID : 2020-05-21_ HD 60147227 0001

Report no. : 10919665-100

Dear Madame or Sir,

**Update of information to Certificate no. HD 60147227 0001, issued on 03.12.2021**

The change notification received on 10.10.2021 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.
We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

**Revised Manufacturer name**

| | |
|---|---|
| Old Manufacturer name: | Shenzhen JCR Technology Limited Company |
| New Manufacturer name: | Shenzhen JCR Medical Technology Limited Company |

Best regards,

Dipl.-Ing. W. Hsu

Certification body

MS-0045446 rev. 0

TÜV Rheinland
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# EC Certificate

## Directive 93/42/EEC Annex II, excluding Section 4
## Full Quality Assurance System
## Medical Devices

TÜVRheinland®

**Registration No.:** HD 60147227 0001

**Report No.:** 17063018 007

**Manufacturer:**

Shenzhen JCR Technology
Limited Company
101, Building 1, Plant B, No. 1, Tianfu
Road, Tianliao Community, Yutang Street
Guangming District
Shenzhen, Guangdong
518132 Guangdong
P.R. China

**Products:**

Disposable Pressure Transducers

Replaces Approval, Registration No.: DD 60127887 0001

**Expiry Date:** 2023-05-01

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2020-05-21

**Date:** 2020-05-21

Notified Body

Wenxiang Zhang

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle III

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.