Business Stream Products
Certification Department

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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.