

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

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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.

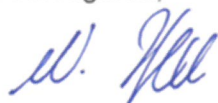
We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

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

TÜV Rheinland  
LGA Products GmbH

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Chairman of the  
Supervisory Board

Dipl.-Ing. Ralf Scheller

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

**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 - 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.