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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-MDR-099

Product Service

# EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

## No. G21 062384 0015 Rev. 00

**Manufacturer:**

**Zhangjiagang Hengya Plastic Products Co., Ltd.**
South Side of Shanzheng Road
Shanzheng Village, Jingang Town
215631 Zhangjiagang City
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000028789

**Authorized Representative:**

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.
As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G21 062384 0015 Rev. 00

**Report No.:** SH2313601
**Valid from:** 2023-09-25
**Valid until:** 2028-09-24

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2023-09-25


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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## No. G21 062384 0015 Rev. 00

| | |
|---|---|
| **Classification:** | Class I |
| **Device Group:** | T01020202 - POLYETHYLENE EXAMINATION / TREATMENT GLOVES |
| **Device Properties:** | MDS 1005.2 - Sterilisation by irradiation |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | Please see detail information in certificate |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2023-09-25 | SH2313601 | Initial issuance |


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