EU Quality Assurance Certificate CN24/00000712

The management system of

Changzhou Hualian Health Dressing Co., Ltd.

No. 55 Yuejin Road, Zouqu Town, Changzhou City, Jiangsu Province, 213144, P.R. China
SRN: CN-MF-000021134
has been assessed and certified as meeting the requirements of

MDR EU Quality Assurance certificate (Annex XI Part A)

For the following products
The scope of Registration appears on page 2 of this certificate

This certificate is valid from 07 February 2024 until 31 January 2029 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 July 2028
Issue 2. Certified since 31 January 2024
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Virginie Siloret
Global Medical Device Certification Manager

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Changzhou Hualian Health Dressing Co., Ltd.

MDR EU Quality Assurance certificate (Annex XI Part A)

Class Is device (MDS1005)
Sterile Adhesive Dressing
[MDN1204 - Basic UDI-DI: 69417626010UW]

Sterile Bandage
[MDN1204 - Basic UDI-DI:69417626012V2]

Disposable Sterile Medical Face Mask
[MDN1214 - Basic UDI-DI: 69417626013V4]

Conditions for & limitation to the validity of the certificate:
For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability, or measurement function).

For placing on the market of Class IIb or Class III devices covered by this certificate an EU Type Examination Certificate according to Annex X is required.

List of examinations and tests performed, which may include reference to relevant CS and harmonized standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation:
N/A
Certification is based on following reports: CN/SZH/263048 - CTC 1.9
Authorized representative Name and address (if relevant): Shanghai International Holding Corp. GMBH (Europe), Eiffestrasse 80, 20537 Hamburg, Germany
Previous certificate number: N/A
Change in between this certificate and previous one: Corrected Typo for Basic UDI-DI for the device Sterile Adhesive Dressing

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Changzhou Hualian Health Dressing Co., Ltd.

MDR EU Quality Assurance certificate (Annex XI Part A)

Issue 2
Sites
Changzhou Hualian Health Dressing Co., Ltd. No. 55 Yuejin Road, Zouqu Town, Changzhou City, Jiangsu Province, 213144, P.R. China
Jiangsu Excellence Medical Supplies Co., Ltd. Zouqu Industrial Zone, Zouqu Town, Zhonglou District, Changzhou City, Jiangsu Province, 213144, P.R. China

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