Declaration of Conformity

Legal Manufacturer	Changzhou Hualian Health Dressing Co.,Ltd No.55 Yuejin Road, Zouqu Town, 213144 Changzhou, PEOPLE'S REPUBLIC OF CHINA
EC Representative	Shanghai International Holding Corp.GmbH（Europe） Eiffestrasse 80, 20537 Hamburg Germany
Product	Sterile Adhesive Dressing
Classification	Class I sterile, Rule 4

European Union Regulations:

European Representative

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the following EU Council Directive(s) as transposed into national laws.

General applicable directives:

Medical Devices REGULATION(EU)2017/745

Certificate Route	Annex XI Part A
Notified Body	SGS Belgium NV NB1639 SGS House Noorderlaan 87 2030 Antwerp Belgium
Certificate n	CN24/00000712
First Issued(Place/Date)	2024-02-07

Australian Regulations:

This declaration is made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian **Therapeutic Goods(Medical Devices) Regulations 2002** relating to the stated devices.

For each kind of medical device that is supplied sterile and to which the Conformity Assessment Procedures(not requiring assessment by Secretary) have been applied, the Production Quality Assurance Procedures have also been applied, Each kind of medical device complies with the applicable provisions of the essential principles and the classification rules before being supplied.

All supporting documentation is retained at the premises of the manufacturer.

Authorised Signatory: **Rita zhu**

General Manager

Changzhou China
Place

Date:2024.09.20

Declaration of Conformity

Item Code	Dressing Size(cm)	Pad Size(cm)	UDI-DI(EACH)	UDI-DI(BOX)	UDI-DI(CASE)
MSCE3223	5x7	3x4	(01)10888277607330	(01)30888277607334	(01)40888277607331
MSCE3278	6.5x8	5x3.5	(01)10888277604827	(01)30888277604821	(01)40888277604828
MSCE3246	10x15	5x10	(01)10888277607347	(01)30888277607341	(01)40888277607348
MSCE32410	10x25	5x20	(01)10888277604810	(01)30888277604814	(01)40888277604811
MSCE32414	10x35	5x30	(01)10888277604834	(01)30888277604838	(01)40888277604835
MSEC3244	10x10	6x6	(01)10888277604797	(01)30888277604791	(01)40888277604798
MSCE3248	10x20	5x15	(01)10888277604803	(01)30888277604807	(01)40888277604804
MSCE3234	8x10	5x4	(01)00888277440589	(01)30888277445080	(01)40888277445087
MSCE32412	10*30	25x5	(01)00888277445096	(01)30888277445097	(01)40888277445094

GMDN: 34864- Adhesive bandage