

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
11196-2017-CE-RGC-NA-PS Rev 1.0

Project No.:
PRJC-542120-2016-PRC-CHN

Valid Until:
27 May 2024

This is to certify that the quality system of:

Zhejiang Haichuang Medical Device Co., Ltd

1st Floor, 146 East ChaoFeng Road, Yuhang Economic and Technological Development Area, Yuhang District, Hangzhou, China

For design, production and final product inspection/testing of:
SURGICAL INCISION CLOSURE SET

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN
ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE
93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 05 August 2020



For:
DNV GL PRESAFE AS
Notified Body No.: 2460

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Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	22 August 2019
1.0	Information of EU Representative changed	05 August 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical Incision Closure Set	5HWH-2A, 5HWH-4A, 5HWH-6A, 5HWH-8A, 5HWH-10A, 5HWH-12A, 5HWH-16A, 5HLS	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Zhejiang HaiChuang Medical Device Co., Ltd.	1st Floor,146 East ChaoFeng Road. Yuhang Economic and Technological Development Area, Yuhang District, Hangzhou, China

EU Representative

Llins Service & Consulting GmbH, Obere Seegasse 34/2, 69124Heidelberg, Germany

