

盐城汇达医疗器械有限公司

YANCHENG HUIDA MEDICAL INSTRUMENTS CO.,LTD.

江苏省盐城市盐东镇庆丰工业园西园

Qingfeng Industrial Park, Yandong, Yancheng city, Jiangsu province, P.R.China

EC DECLARATION OF CONFORMITY

Manufacturer's Name: YANCHENG HUIDA MEDICAL INSTRUMENTS CO.,LTD.

Manufacturers Address: Qingfeng Industrial Park, Yandong, Yancheng city, Jiangsu province, P.R.China

European Representatives:

Renault- Petersen Limited 5, Bankside, Hanborough Business
Park, Witney OX29 8LJ UK TEL:+44 1993882779 FAX:+44
1993880110, ZIP CODE:OX29 8LJ

Name of Device

stainless steel blades, scalpels,

Type:

stainless steel surgical blades, 10#, 11#

LOT

HUI-24

UMDNS code

15558

Classification:

2A

Conformity Assessment Procedure: Annex V

Conformity Route:

Self Declaration

We herewith declare in our own responsibility that the above mentioned products with CE mark meet the provisions of the EC Council Directive 93/42/EEC Annex V, Article 3. All supporting documentations are retained under the premise of manufacturer(head of Quality department).

General applicable directives: Council Directive 93/42/EEC concerned medical devices, amended by Directive Annex V, Article 3.

Referenced standard:

EN ISO 13485:2016 +AC:2007

Notified Body:

TUV Rheinland

Quality Management System

ISO 13485:2016

Cert valid until:

09.05. 2023

Competent Authority:

Greatcare Medical GmbH Gildenweg 6,50354 Hurth, Germany
TEL:0049-2233-9666-416 FAX:0049-2233-9666-418

Registration Date:

10.05.2018

Registration NO.:

DD601284260001

Date:

29, JUN, 2018

Signature and Company seal

Name: Mr Ligang

Position: Senior Factory Manager

