

HS/CE-01-07

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

HAINING HENGSHANG KNITTING CO., LTD
2F, No.10 Chaoyang Road, Yuanhua Town, 314416, Haining
City, Zhejiang Province, China

Trademark:



SRN:

CN-MF-000040841

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

Underpad

Product Name:

Underpad

Product code / Catalogue number:

18"×24", 24"×30", 24"×36", 31"×36", 30"×36", 34"×36", 34"×52",
36"×48", 36"×41", 36"×52", 36"×60", 36"×72", 35"×80", 48"×60",
48"×72", 60"×60", 60"×72", 72"×72", 34"×56", 44"×54", 28"×36",
18"×24", 24"×30", 24"×36", 31"×36", 30"×36", 34"×36", 34"×52",
36"×48", 36"×41", 36"×52", 36"×60", 36"×72", 35"×80", 48"×60",
48"×72", 60"×60", 60"×72", 72"×72", 34"×56", 44"×54", 28"×36",
50cm*50cm, 60cm*90cm, 80cm*90cm, 90cm*100cm,
90cm*120cm, 90cm*150cm, 90cm*180cm, 100cm*100cm,
150cm*180cm, 180cm*200cm, 41"×41"

Basic UDI:

697729039UnderpadCP

Classification acc. to MDR Ax. VIII:

Class I, rule 1

Applied Standard & Common Specification:

EN ISO 14971:2019、EN 13795-1:2019

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Jiang Mengdie

Jiang Mengdie,
General Manager

Haining

Haining, March 1, 2024