



Dong Bang Medical co.,Ltd

40, 30, Saneopdanji-gil, Ungcheon-Eup, Boryeong-si, Chungnam-do, Korea

Tel : +82(41) 933-7785 Fax : +82(41) 934-5715

EC Declaration of Conformity

Manufacturer: Dong Bang Medical co.,Ltd

40, 30, Saneopdanji-gil, Ungcheon-Eup, Boryeong-si, Chungnam-do, Korea

European representative: Meridius Medical Europe Ltd.

Unit 3D, North Point House, North Point Business Park, New Mallow Road, Cork, T23 AT2P, Ireland

Tel. : +353 212066448

Trade Name: Dong Bang Acupuncture Needles

Model Name: Sterile Single-Use Acupuncture Needles, Sooji chim Needle(Hand-Needle), Press Track Needles and Intradermal Needle

Classification: Class IIa

According to the Rule 6 of Classification Criteria,

Annex IX, Directive 93/42/EEC as amended by 2007/47/EC

UDI : Refer to the Attachment.

APPLICABLE NORMATIVE REFERENCES:

MDD 93/42/EEC as amended by 2007/47/EC, EN ISO 14971[2012], EN 1041 [2008], ISO 9001 [2009]

EN ISO 13485 [2012], EN ISO 10993-1 /AC:2010 , EN ISO 11135-1[2007], EN ISO 11607-1 [2009]

EN ISO 11607-2 [2006], EN ISO 10993-7 :2008/AC:2009, ISO 14644-5 [2007], EN ISO 11737-2:2009

ASTM F1980[2007], ISO 683-13 [1986], EN 980:2008, EN ISO 10993-5:2009, ISO 10993-10:2010

EN ISO 11137-1 :2015, EN ISO 11137-2 : 2015

Conformity Assessment Route: Annex II (excluding section 4)

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC, ISO13485, ISO9001 for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Notified Body: SGS Belgium NV, Notified Body 1639

SGS House Nooderlaan 87 2030 Antwerp Belgium

EC Certificate Full Quality Assurance System: Certificate KR19/81826307

Date of issue: Feb 03, 2020

Signature:

Keun Sik, Kim / President

For on behalf of Dong Bang Medical co.,Ltd.