

DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

This Declaration of Conformity is only valid with record of final inspection for a specific lot. / device enclosed.

Unique identification number of the D.o.C: DB-DOC-001 Rev.0

Issued date : Sep 10, 2020

MANUFACTURER: DONGBANG MEDICAL Co.,Ltd.
40, 30, Saneopdanji-gil, Ungcheon-Eup, Boryeong-si, Chungcheongnam-do, Korea
Zip Code : 33506
Tel. +82-41-933-7785

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

PRODUCT (Model/type): Sterile Acupuncture needle, single-use
MODEL/TYPE: Refer to the Attachment.
BRAND NAME: Dong Bang Acupuncture Needle
GMDN Code: 34175
CLASSIFICATION: Class IIa according to MDD/93/42/EEC amended by 2007/47/EC (Annex IX, Rule 6)

CONFORMITY ASSESSMENT ROUT: Annex II (Section 4 excluded)

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AMENDED BY 2007/47/EC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: Refer to the Attachment.

NOTIFIED BODY: Notified Body Number 0068,
MTIC InterCert S.r.l.
Via G.Leopardi, 14 20123 Milano (MI), ITALY

(EC) CERTIFICATE(S): -

START OF CE-MARKING -

PLACE, DATE OF ISSUE: In Boryeong-si, Sep. 10, 2020

SIGNATURE:

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Keun Sik, Kim / C.E.O

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