

Declaration of Conformity



according to the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC

Manufacturer : Dongsan Medical Corporation

Address : 81-2 deoki-ri, bongdam-eup Hwaseong-si, Kyonggi-do, South Korea

European Representative : Nemko AS

Address : Nemko AS, Gaustadalléen 30, N-0373 Oslo, Norway

Product : Scrub station

Model name : SSS-111, 112, 113 (Option : Sensor type)

Classification : Class I by Rule 12 of Annex IX, Medical Device Directive 93/42/EEC as amended by 2007/47/EC

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards:

EN ISO 15223-1:2012 EN 980:2008

EN ISO 13485:2012 EN 1041:2008

EN ISO 14971:2012 EN 60601-1-2:2007

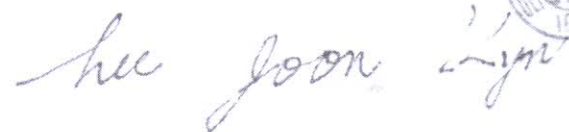
MEDDEV 2.12-1Rev.8 MEDDEV 2.7.1 Rev.3

MEDDEV 2.12.2 Rev2

This Declaration of Conformity is based on the EC Directives 93/42/EEC as amended by 2007/47/EC.

Dongsan Medical Corporation

President : Jun Kyu Lee



Issuing Date : August 16th 2017

SAO Y BẢN CHÍNH



Giám Đốc
NGUYỄN TRUNG TÍN