T-C TAE-CHANG INDUSTRIAL CO.,LTD

EC Declaration of Conformity

TAE-CHANG INDUSTRIAL CO.,LTD.

8-18, Bojeokdong-gil,Useong-myeon,Gongju-si,Chungcheongnam-do,Korea

As per Annexure – IX of the Medical Device Directive comply with the productstandards / requirements and, meet the essential requirements according to Annexure- I of the Council Directive 93/42/EEC of 14th June 1993 as amended by 2007/47/EC concerning medical devices.

Product name : STERILE SPINAL NEEDLE

Model code : SP.PP , SP.QB

Medical Device Class : Class Ⅲ

Conformity Assessment Procedure was carried out according to Annexure - II including section 4 (Module – H1) of the MDD and is certified by the following Notified Body.

Name, Address & No. : Belgium NV, Noorderlaan 87 BE02030 Antwerpen Belgium
Notified Body Number 1639

CE Certificate No. : KR19/81826338

EC Representative : **Interkotra GmbH**

Address : Kurfuerstenplatz 34 D-60486 Frankfurt am Main Germany

Tel : +49 (0)69-778914

DATE : Aug, 18. 2021

충남 공주시 우성면 보적동길 8-18
태창산업주식회사
대표이사 박 정 연

T-C

President on behalf of TAE-CHANG INDUSTRIAL CO.,LTD

8-18, Bojeokdong-gil,Useong-myeon,Gongju-si,Chungcheongnam-do,Korea