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

Medical Device Class : Class Ⅲ

GMDN code : 35212 (Spinal needle, single-use)

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 : **KTR GmbH**
Mergenthalerallee 77,65760,Eschborn, Germany
Tel : +49-6168-887-170

DATE : Apr, 26. 2023

Signature and stamp of Manufacturer

T-C

President on behalf of TAE-CHANG INDUSTRIAL CO.,LTD
8-18, Bojeokdong-gil,Useong-myeon,Gongju-si,Chungcheongnam-do,Korea

Attached national standard List

No	Standard identification	Issued date	Standard name
1	EN ISO13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
2	EN ISO14971	2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
3	EN ISO10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)
4	EN ISO10993-4	2017	Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
5	EN ISO10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
6	EN ISO10993-7	2008/AC:2009	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
7	EN ISO10993-10	2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
8	EN ISO10993-11	2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
9	EN ISO11135	2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
10	EN ISO11138-1	2017	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
11	Korea Pharmacopoeia	9th	General testing method <9>-Sterility testing
12	EN ISO11138-2	2017	General testing method <56>-Extract testing for plastic container of medicinal drug
			Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
13	EN ISO14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
14	EN ISO14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
15	EN ISO11607-1	2017	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
16	EN ISO11607-2	2017	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
17	EN ISO11737-1	2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products

18	EN ISO11737-2	2009	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the validation of a sterilization process
19	*EN ISO6009*	*2016*	Hypodermic needles for single use -- Color coding for identification
20	*EN ISO7864*	*2016*	Sterile hypodermic needles for single use - Requirements and test methods
21	EN ISO9626	2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
22	KS D 3698	2008	Cold rolled stainless steel plates, sheets and strip
23	EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
24	EN1041	2008	Information supplied by the manufacturer of medical devices
25	Europe Pharmacopoeia	2002	Europe Pharmacopoeia
26	ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
27	United state Pharmacopoeia	29th	“GEL-CLOT TECHNIQUES” of USP29 <85> Bacterial Endotoxins Test
28	ISO80369-6	2016	Small bore connectors for liquids and gases in healthcare applications-Part6:Connectors for neuraxial applications
29	ISO 80369-7	2016	Small-bore connectors for liquids and gases in healthcare applications -Part 7:Connectors for intravascular or hypodermic applications
30	ISO80369-20	2015	Small bore connectors for liquids and gases in healthcare applications-Part20:Common test methods