Declaration of Conformity

Manufacturer :	Changzhou Weite Medical Equipment Co., Lt d.
Office address:	Wugang Village, Zhenglu Town, Changzhou, 213115 Jiangsu, China
Telephone:	+86-519-88673628
Authorized representative in the European community:	Caretechion GmbH
Office address:	Niederrheinstr.71,40474 Duesseldorf, Germany
Telephone :	+49 211 3003 6618
Product name:	Sterile Nelaton Catheters;
Type or size:	1) Tiemann Fr/CH: 08, 10, 12, 14, 16, 18 & 20 2) Nelaton Fr/CH: 08, 10, 12, 14, 16, 18 & 20 3) Female Fr/CH: 08, 10, 12, 14, 16 & 18 4) Rectal Fr/CH: 22, 25, 28 & 30
Product ref. codes:	
Tiemann :	4500200, 4500201, 4500202, 4500203, 4500204, 4500205 & 4500206.
Nelaton:	4500207,4500208,4500209,4500210,4500211,4500212,4500213,
Female :	4500214, 4500215, 4500216, 4500217, 4500218 & 4500219.
Rectal:	4500300, 4500301, 4500302 & 4500303.
GMDN Code:	10734
QMS REC:	WI-SJ(I)-01–07, Rev. A/1
Classification (MDD Annex IX):	Class Is, Rule 5
Conformity Assessment Route:	MDD 93/42/EEC, Annex VII coupled with Annex V
Applicable directive:	Council Directive 93/42/ EEC of 14th June 1993 concerning medical devices, amended by Directive 2007/47/EC of 5th September 2007.
Harmonized standard(s):	EN ISO 10993-1:2020, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-7:2008,EN ISO 10993-11:2018, EN ISO 11135:2014/A1:2019, EN ISO 11138-2:2017, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 13485:2016/A11:2021, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 15986:2011, EN 62366-1:2015/A1:2020, EN 556-1:2001 & EN ISO 20417:2021
Notified Body:	TÜV Rheinland LGA Products GmbH
Identification No.:	0197
EC-Certificate Reg. No.:	DD 2068188-1
Certificate expiry date:	2024-05-26
Contact on technical documentation:	Changzhou Weite Medical Equipment Co., Ltd.

We, the manufacturer, hereby declare that above mentioned products meet the transposition into national law as per the provisions of the EC Council Directive 93/42/ EEC of 14th June 1993 amended by Directive 2007/47/EC of 5th September 2007.

Production period covered by this issued declaration: 20st October 2022 to 19st October 2023

Signed :

Name & position : (name of person)

On behalf of: Changzhou Weite Medical Equipment Co., Ltd.

(Company seal)