

EU DECLARATION OF CONFORMITY
MDR 2017/745

NINGBO KS MEDICAL TECH CO.,LTD
No. 258, Dieyuan Road, Yinzhou District, Ningbo, China, 315100
SRN: CN-MF-000007638

Hereby declare under their own responsibility that

MEDICAL DEVICES CALLED
"ROUND DRUMS",

BASIC UDI-DI: 69343741002615H

MANUFACTURED BY NINGBO KS MEDICAL TECH CO.,LTD

ARE COMPLIANT WITH THE ESSENTIAL SAFETY AND PERFORMANCE
REQUIREMENTS SET FORTH IN ANNEX I OF THE MEDICAL DEVICES
REGULATION 2017/745.

Classification (MDR, Annex VI): Class I, Rule 13.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex II + Article 19 of MDR(EU) 2017/745.

We herewith under our sole responsibility declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation(EU)2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation(EC)No 178/2002 and Regulation (EC)No 1223/2009 and repealing Council directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN 12184:2014, EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 14971:2012,
EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010,
EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015
EN 62304:2006+A1:2015.

Torre de' Picenardi 15.03.2022

(place and date of issue)

NINGBO KS MEDICAL TECH CO.,LTD

(Authorized company seal)

Annex list of devices covered by this declaration

宁波开市医疗科技有限公司

NINGBO KS MEDICAL TECH CO.,LTD

Rev. 01 dated 15.03.2022

Code	Description
KSM-MT7 304	STAINLESS STEEL STERILIZATION BOX PERFORATED 6" (15.5*10*5.5CM)
KSM-MT7 304	STAINLESS STEEL STERILIZATION BOX PERFORATED 8" (21.5*12*5.5CM)
KSM-MT7 304	STAINLESS STEEL STERILIZATION BOX PERFORATED 9" (24*16*5.5CM)
KSM-MT7 304	STAINLESS STEEL STERILIZATION BOX PERFORATED 11.5" (31*21*5.5CM)
KSM-MT8 304	STAINLESS STEEL GAUZE STERILIZER INSTRUMENT CASE AUTOCLAVING 17*14.5CM
KSM-MT8 304	STAINLESS STEEL GAUZE STERILIZER INSTRUMENT CASE AUTOCLAVING 20*16CM
KSM-MT8 304	STAINLESS STEEL GAUZE STERILIZER INSTRUMENT CASE AUTOCLAVING 23*17.5CM
KSM-MT8 304	STAINLESS STEEL GAUZE STERILIZER INSTRUMENT CASE AUTOCLAVING 26*19.5CM
KSM-MT8 304	STAINLESS STEEL GAUZE STERILIZER INSTRUMENT CASE AUTOCLAVING 30*20.5CM

Rev. 01 dated 15.03.2022

宁波市医疗科技有限公司
NINGBO KS MEDICAL TECH CO.,LTD