EU Declaration of Conformity

Manufacturer Name: Kingstar Medical (Xianning) Co., Ltd.
Manufacturer Address: No. 79 Yong'andong Road, Xian'an District 437100, Xianning City, Hubei Province, the People's Republic of China.
Location of Manufacturer: Xianning City, Hubei Province, China.
Authorized Representative: Shanghai International Holding Corp. GmbH (Europe)
Address of their Registered Place of Business: Eiffestrasse 80, D-20537, Hamburg, Germany
Location be established: Germany

SRN of the manufacturer: CN-MF-000006015

Registered Trade Name / Mark: KINGSTAR
Name of the device: Nonsterile Tongue Depressor
CND Code: V9001, TONGUE DEPRESSORS, SINGLE-USE
UMDNS Code: 14066 (Tongue Depressors)
Basic UDI-DI: 6971872201141000M2

Intended Purpose: intended displace the tongue to facilitate examination of the surrounding organs and tissues.

Risk Class of the Device: Class I, based on Rule 5 of Annex VIII of the Regulation (EU) 2017/745.
All invasive devices with respect to body orifices, other than surgically invasive devices, — class I if they are intended for transit use;

The Conformity Assessment Procedure Performed: According to Article 19 of the Regulation (EU) 2017/745, draw up this EU declaration of conformity which contain the information set out in Annex IV of the Regulation (EU) 2017/745.

Identification of the device: Please find in Annex I.

Declaration: This declaration of conformity is issued under the sole responsibility of Kingstar Medical (Xianning) Co., Ltd. We hereby declare that the medical device specified above meet the provision of the Regulation (EU) 2017/745. This declaration is supported by the quality system approval to ISO 13485 by TÜV SÜD Product Service GmbH.

All supporting documentation is retained at the premises of the manufacturer.

Signed for and on behalf of:
Place of Issue: Xianning City, Hubei Province, China.
Date of Issue: 2021.11.05
Print Name: Yuanqiang Ren
Function: Management Representative
Signature: 

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Doc. No.	KSX/TD-TDN-017-183	Title	EU Declaration of Conformity of Nonsterile Tongue Depressor		
Ver./Rev.No.	A/1	Issued Date	2021.11.05	Page/Total	2 / 2

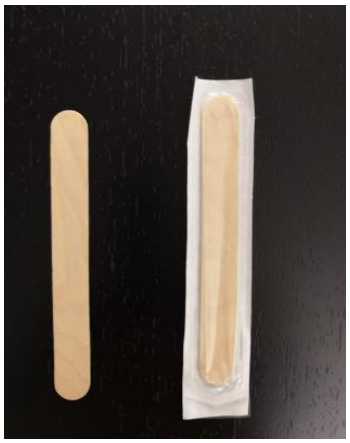
Annex I --- Identification of the Device Covered by the EU Declaration of Conformity

Identification of the Device

Table --- Identification of the Device

No.	Catalogue Number	Specification	Packaging Configuration
1	9802	Tongue Depressors, 15cm, wooden	100pc/box, 20 boxes/case

Photograph of the Devices



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