EU Declaration of Conformity

Manufacturer: Goodwood Medical Care Ltd

Address: 3-919, Yongzheng Street, Jinzhou District, Dalian Liaoning, China
SRN: CN-MF-000016564

Whose single Authorized Representative:
CMC Medical Devices & Drugs S.L.
Address: C/ Horacio Lengo No18, CP 29006, Málaga, Spain
SRN:ES-AR-000000293

As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device:

the STATE medical device:/	Tongue Depressors
Model:/	GW-1102/GW-1105/GW-1106/GW-/1108/GW-1110/GW-1110D
Basic UDI-DI:/	697312826GW010DT
Of class:/	Class I ,Rule 5, Subclause 5.1.1,indent 1
Intended purpose:/	A tongue depressor is a device intended to displace the tongue to facilitate examination of the surrounding organs and tissues Active site： Oral cavity
CS reference:/	None

meets the provisions of Regulation EU 2017/745(MDR) and its transportations in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /
Applicable harmonized standards are: /
EN ISO13485:2016/EN ISO14971:2019/EN ISO 15223-1:2016/ISO 10993-1:2018/EN ISO10993-5:2009/EN ISO 10993-10:2013

Dalian, 2023-01-10

CEO

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Ort, Datum / Place, date /
Lieu, date / Luogo, data

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Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

Medline International France SAS
5 Rue Charles Lindbergh,
44110, Châteaubriant, France
www.medline.com

Equivalency between Goodwood article # and Medline article # for Tongue Depressor

To whom it may concern

Medline hereby confirm the equivalency detailed in the table below:

Medline Item code	Item description	GW Model	GW Item code
727020	WOODEN TONGUE DEPRESSOR, 15CM	GW-1110	GW-1110

Therefore, the attached EC Declaration of conformity issued by Goodwood Medical Care Ltd is applicable for Medline's article number mentioned in the table above.

Your sincerely

Hrutuja Nibe

Digitally signed by Hrutuja Nibe
DN: cn=Hrutuja Nibe, o=Medline Industries India, Pvt. Ltd., ou=QRA, email=HNibe@medline.com, c=IN
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Medline's signature

Goodwood's signature

MU Chengcai
2024.01.30

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