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:/	Sterile Tipped Applicators
Model:/	GW-1200C01/GW-1200C02/GW-1200C03/GW-1200P01/GW-1200P02/ GW-1200P03/GW-1200R01/GW-1200R02/GW-1200R03
Basic UDI-DI:/	697312826GW001DS、697312826GW016E7、697312826GW018EB 697312826GW017E9、697312826GW020DW、697312826GW025E8、 697312826GW019ED、697312826GW027EC、697312826GW029EG、 697312826GW024E6、697312826GW031E3、697312826GW033E7、 697312826GW026EA、697312826GW035EB、697312826GW030DZ、 697312826GW028EE、697312826GW032E5、697312826GW034E9
EMDN code:/	A99：DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION - OTHER
Of class:/	Rule1, subclause 4.1
Intended purpose:/	It is a device intended for medical purposes that consists of an absorbent swab on a plastic stick. The device is used to apply medications to, or to take specimens from, a patient. Active site： Surface skin wipe/Sampling
CS reference:/	None

is in conformity with Regulation (EU) 2017/745 and with any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity. The declaration is valid in connection with the “final inspection report” of the device. /

Conformity assessment procedure: /	MDR Annex II, III and Annex XI (Part A)
Notified Body: /	TÜV Rheinland LGA Products GmbH Tillystraße 2 , 90431 Nürnberg, Germany CE 0197
Registration No.: /	244384642-200
Issue Date:/	2023-01-06
Expiry Date:/	2027-11-03

Dalian, 2023-01-10

CEO

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

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

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44110, Châteaubriant, France
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Equivalency between Goodwood article # and Medline article

07 June 2023

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
830000A	APPLICATOR COTTON, NST, 15CM SMALL TIP, 100/PK		GW-1255
830010A	APPLICATOR COTTON, ST, 15CM SMALL TIP, 2/PK	GW-1200C01	GW-1219
831510A	APPLICATOR COTTON, ST, 15CM LARGE TIP, 2/PK	GW-1200C02	GW-1237
831578A	APPLICATOR COTTON, NST, 15CM LARGE TIP, 50/PK		GW-1226

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

Your sincerely

Medline's signature

Charlotte Lambert

Digitally signed by Charlotte Lambert
DN: cn=Charlotte Lambert, o=Medline International France, ou, email=charlotte.lambert@medline.com, c=FR
Date: 2023.06.07 14:33:00 +02'00'

Goodwood's signature

2023.06.08.

Document Number: EU1-00004-F-00030 Document Title: FINT.444 - Template for Position paper Revision: 2

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