EU Declaration of Conformity

Manufacturer: Goodwood Medical Care Ltd

SRN

Address: 1-2 Floor, 3-919, Yongzheng Street, Jinzhou District, Dalian Liaoning, China

SRN

Whose single Authorized Representative:
CMC Medical Devices & Drugs S.L.
CN-MF-000016564
Address: C/ Horacio Lengo No18, CP 29006, Málaga, Spain
ES-AR-000000293

WE, AS THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.
HEREWITH DECLARE THAT /

the STATE medical device:/	Cotton Tipped Applicators
Model:/	GW1255/GW1226/GW1213/GW1226A/GW1255P/GW1226P/ GW1226AP/GW1226R/GW1229/GW1226AR
GMDN Code:/	15066
Basic UDI:_	697312826GW007E6
Of class:/	I, RULE 5(5.1/1) according to Annex VIII of Regulation EU 2017/745(MDR)

meets the provisions of Regulation (EU) 2017/745 (MDR) which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

Conformity assessment procedure: Annexes II + III with Part A of Annex XI, Medical Device Regulation （EU） 2017/745

Dalian, 2021-05-20

CEO: LEO

_____

_____

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

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

© 2020 Medline Industries Inc. or one of its subsidiaries. All rights reserved.