Medline International France SAS
5 rue Charles Lindbergh
44110 Châteaubriant
France

Tel: + 33 (0) 2 40 81 38 04
Fax: + 33 (0) 2 40 81 56 34

www.medline.com

Equivalency Between Applimed article # and Medline article

30 November 2017

To Whom it may concern,

Medline hereby confirm the equivalency detailed in the table below:

Medline Codes	Equivalent Applimed Codes	Product description
831578	1422279	Applicateur PP 150x4mm, grosse tête coton forme continentale / Big Non Sterile Cotton Applicator
830000	1001208	Applicateur bois 150x2,2mm, petite tête coton/ Small Non Sterile Cotton Applicator

Therefore, the attached EC Declaration of conformity issued by Applimed SA is applicable for the article numbers 831578 and 830000.

Your sincerely,

The QA/RA department, Medline

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FINT.444 Révision n°00 Date d'application : 25 Sep 12

APPLIMED SA

Zone industrielle
Route de Pra de Plan 1
CH-1618 CHATEL-ST-DENIS
Switzerland

TEL : +41 (0) 21 948 92 74
FAX : +41 (0) 21 948 90 36
E-mail : info@applimed.ch
Website : www.applimed.ch

EC Declaration of Conformity

Applimed SA

ZI, route Pra de Plan 1, CH-1618, Châtel Saint Denis,

SRN: Not yet available.

Declare, under their sole responsibility, that the medical devices in the family named Non-sterile Applicators indicated in the annexed table:

- are manufactured by **Applimed SA**,
- are non-sterile medical devices
- have been identified as medical devices in risk class I according to rules 4 and 5 in Annex VIII of Regulation (EU) 2017/745
- meet the applicable provisions, in particular the General Safety and Performance Requirements of the Regulation (MDR) 2017/745 and harmonised standards ISO 14971:2012, ISO 15223-1:2016, and ISO 10993-1:2018
- and are subject to the conformity assessment procedure set out in Annexes II & III, under the self-certification of Applimed SA.
- All supporting documentation is retained at the premises of the manufacturer.

Basic UDI-DI: 0764017844NAppApp0S3

European Representative: Dansu A/S

Address: Sandbakken 1-3, Ganløse, DK-3660 Stenløse, Denmark

SRN: Not yet available.

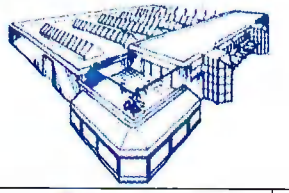
Name: MOTTER, Giancarlo

Function: Regulatory Affairs Manager (PRRC)

Place: Châtel-St-Denis

Date: 11.06.2021

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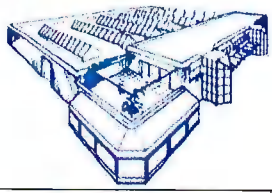
TEL : +41 (0) 21 948 92 74
FAX : +41 (0) 21 948 90 36
E-mail : info@applimed.ch
Website : www.applimed.ch

Group	Catalog N°	Description
Aluminium Applicator	1801183	Applicator with Aluminum Stick, 150x0.9 mm, Cotton head
	1801193	Applicator with Aluminium Stick, 150x0.9 mm, Viscose head
	1806197	Applicator with Aluminum Stick, 150x0.9 mm, Polyester head
PP Applicator	1401219	Applicator with Polypropylene Stick, 150x2.5 mm, Small cotton head
	1402244	Applicator with Polypropylene Stick, 150x2.5 mm, small Viscose head
	1402250	Applicator with Polypropylene Stick, 150x2.5 mm, small Viscose head
	1403001	Applicator with Polypropylene Stick, 94x2.5 mm, small Viscose head (5-5.5mm)
	1421282	Applicator with Polypropylene Stick, 150x4 mm, big Cotton head, American Shape
	1421283	Applicator with Polypropylene Stick, 150x4 mm, big Cotton head, American Shape
	1421504	Applicator with Polypropylene Stick, 300x4 mm, Continental shape, Big Cotton head
	1422278	Applicator with Polypropylene Stick, 150x4 mm, Big Cotton head, Continental Shape
	1422279	Applicator with Polypropylene Stick, 150x4 mm, Big Cotton head, Continental Shape
	1422280	Applicator with Polypropylene Stick, 150x4 mm, Big Cotton head, American Shape
	1422283	Applicator with Polypropylene Stick, 150x4 mm, Big Cotton head, American Shape
	1422286	Applicator with Polypropylene Stick, 100x4 mm, Big Cotton head, Continental Shape
	1422287	Applicator with Polypropylene Stick, 100x4 mm, Big Cotton head, Continental Shape
	1422505	Applicator with Polypropylene Stick, 200x4 mm, Continental shape, Big Cotton head
	1432504	Applicator with Polypropylene Stick, 400x4 mm, Mega Cotton head, American shape
PS Applicator	1202180	Applicator with Polystyrene Stick, Semi-choc, 150x2.5 mm, Small Cotton head
	1202217	Applicator with Polystyrene Stick, 150x2.5 mm, Small Viscose head
	1202218	Applicator with Polystyrene Stick, 150x2.5 mm, Small Viscose head
	1211246	Applicator with Polystyrene Stick, 150x2.5 mm, Small Polyester head
	1211247	Applicator with Polystyrene Stick, 90x2.5 mm, Small Viscose head
	1211248	Applicator with Polystyrene Stick, 150x2.5 mm, Small Polyester head
	1211249	Applicator with Polystyrene Stick, 150x2.5 mm, Small Polyester head

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Group	Catalog N°	Description
	1211251	Applicator with Polystyrene Stick, 150x2.5 mm, Small Polyester head
	1212219	Applicator with Polystyrene Stick, 150x2.5 mm, Small Cotton head
Stainless Steel Applicator	2001192	Applicator with Stainless Steel Stick, 150x0.9 mm, min Cotton head (2.2-2.7mm)
Wood Applicator	1001177	Applicator with Wooden Stick, 150x2.2 mm, Small Cotton head
	1001179	Applicator with Wooden Stick, 150x2.5 mm, Small Cotton head
	1001200	Applicator with Wooden Stick, 150x2.2 mm, Small Cotton head
	1001202	Applicator with Wooden Stick, 150x2.2 mm, Small Cotton head
	1001207	Applicator with Wooden Stick, 150x2.2 mm, Small Cotton head
	1001208	Applicator with Wooden Stick, 150x2.2 mm, Small Cotton head
	1001230	Applicator with Wooden Stick, 150x2.2 mm, Small Cotton head
	1001231	Applicator with Wooden Stick, 150x2.2 mm, Small Cotton head
	1001472	Applicator with Wooden Stick, 200x2.5 mm, Small Cotton head
	1002215	Applicator with Wooden Stick, 150x2.5mm, small Viscose head
	1011124	Applicator with Wooden Stick, 150x2.5 mm, Cotton head (average 7-8mm)
	1011225	Applicator with Wooden Stick, 150x2.2 mm, Cotton head (average 5mm)
	1021245	Applicator with Wooden Stick, 150x2.5 mm, Big Cotton head, Continental Shape
	1021275	Applicator with Wooden Stick, 150x2.5 mm, Big Cotton head, Continental Shape
	1021291	Applicator with Wooden Stick, 150x2.8 mm, Big Cotton head, American Shape
	1021292	Applicator with Wooden Stick, 150x(2.8-3.0)mm, Big Cotton head, American Shape
	1022467	Applicator with Wooden Stick, 200x3 mm, Big Cotton head, Continental Shape
	1031462	Applicator with Wooden Stick, 200x3 mm, Mega Cotton head, American shape