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44110 Châteaubriant
France

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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
830010	1102455	Bâtonnet bois 150x2.2, petite tête coton/ Small Sterile Cotton Applicator
831510	1522277	Applicateur PP 150x4mm, grosse tête coton Forme Continentale/ Big Sterile Cotton Applicator

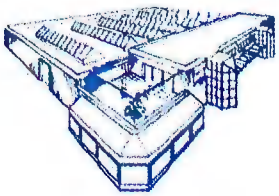
Therefore, the attached EC Declaration of conformity issued by Applimed SA is applicable for Medline's article numbers 830010 and 831510.

Your sincerely,

The QA/RA department, Medline

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



APPLIMED SA

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Switzerland

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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.

Declares that the medical devices named Single Use Sterile Applicators indicated in the annexed table

- are manufactured by **Applimed SA**,
- are Sterile Medical Devices
- are Medical Devices of Class Is rule 4 and 5
- are in compliance with requirements of Annex I of the 93/42/EEC Medical Device Directive (MDD) and standards ISO 14971, ISO 15223-1, EN 1041, EN 868-5, ISO 11607-1, ISO 116072, ISO 11135
- And subject to procedure set out in the MDD 93/42/EEC Annex V (Sterilisation only) under the supervision of Notified Body Number 1639, SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium.

Annex V EC certificate N° CH19/1050 valid from the 16th of December 2019 until the 10th of April 2023, and remains valid subject to satisfactory surveillance audits.

ISO 13485:2016 certificate N° CH12/0135 valid from the 11th April 2021 until the 10th April 2024. Recertification audit due before 12 February 2024.

Basic UDI-DI: 0764017844SAppApp0V2

Authorised Representative: Dansu A/S

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

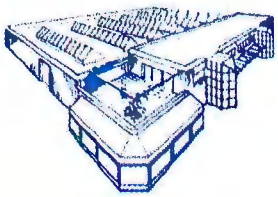
SRN: Not yet available.

Name: MOTTER, Giancarlo

Function: Regulatory Affairs Manager (PRRC)

Place: Châtel-St-Denis

Date: 11.06.2021



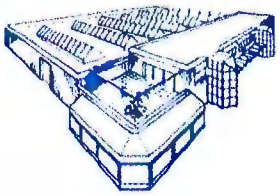
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Group	Article N°	Product/Family name
Metal applicator	1901195	Applicator with Aluminium Stick, 150x0.9 mm, Cotton head (3x17mm)
	1901196	Applicator with Aluminium Stick, 150x0.9 mm, Viscose head
	1901198	Applicator with Aluminium Stick, 150x0.9 mm, Cotton head
	1901199	Applicator with Aluminium Stick, 150x0.9 mm, Cotton head
	1901941	Applicator with Aluminium Stick, 150x0.9 mm, Polyester head
	2101188	Applicator with Stainless Steel Stick, 150x0.9 mm, cotton head
PP applicator	1301266	Applicator with Polypropylene Stick, 75x2.5mm, double small head
	1323000	Applicator with Polypropylene stick, 75x2.5mm, Viscose small head
	1323003	Applicator with Polypropylene stick, 100x2.5mm, Cotton small head
	1501242	Applicator with Polypropylene Stick, 75x2.5mm, Cotton small head, Two Heads
	1501253	Applicator with Polypropylene Stick, 150x2.5mm, Cotton small head
	1501254	Applicator with Polypropylene Stick, 150x2.5mm, Cotton small head
	1501256	Applicator with Polypropylene stick, 150x2.5mm, Cotton small head
	1501257	Applicator with Polypropylene stick, 150x2.5mm, Cotton small head (3.5-4.5 mm)
	1501258	Applicator with Polypropylene stick, 150x2.5mm, Cotton small head (3.5-4.5 mm)
	1501259	Applicator with Polypropylene stick, 150x2.5mm, Cotton small head
	1501280	Applicator with Polypropylene stick, 150x2.5mm, Cotton small head
	1511888	Applicator with Polypropylene stick, 150x4 mm, Cotton big head (R)
	1511889	Applicator with Polypropylene stick, 150x4 mm, Cotton big head (R)
	1512573	Applicator with Polypropylene stick, 150x4 mm, American shape, Cotton big head (R)
	1516206	Applicator with Polypropylene Stick, 150x4 mm, American shape, Cotton big head (R)
	1521286	Applicator with Polypropylene stick, 150x4 mm, Continental shape, Cotton big head

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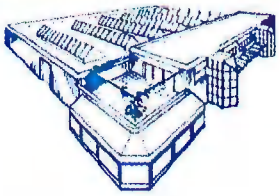
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	1521288	Applicator with Polypropylene stick, 150x4 mm, American shape, Cotton big head
	1521289	Applicator with Polypropylene stick, 150x4 mm, Continental shape, Cotton big head
	1521290	Applicator with Polypropylene stick, 150x4 mm, Continental shape, Cotton big head
	1521294	Applicator with Polypropylene stick, 150x4 mm, Continental shape, Cotton big head
	1521296	Applicator with Polypropylene stick, 150x4 mm, Continental shape, Cotton big head
	1522252	Applicator with Polypropylene stick, 150x4 mm, Continental shape, Cotton big head
	1522277	Applicator with Polypropylene stick, 150x4 mm, Continental shape, Cotton big head
	1532290	Applicator with Polypropylene stick, 200x4 mm, Cotton big head,
PS applicator	1251152	Applicator with Polystyrene stick, 140x4mm, green foam head
	1251154	Applicator with Polystyrene stick, 140x4mm, cross green moss
	1251155	Applicator with Polystyrene stick, 140x4mm, cross blue moss
	1251158	Applicator with Polystyrene stick, 140x4mm, cross blue moss
	1301241	Semi-choc Applicator with Polystyrene stick, 150x2.5mm, small viscose head
	1301265	Semi choc Applicator with Polystyrene stick, 150x2.5mm, small polyester head
Wood applicator	1101171	Applicator With Wooden Stick, 150x2.2mm, small cotton head, sterile
	1101252	Applicator with Wooden Stick, 150x2.2mm, small cotton head
	1101273	Applicator with Wooden Stick, 150x2.2mm, small cotton head
	1101274	Applicator with Wooden Stick, 150x2.2mm, small cotton head
	1101276	Applicator with Wooden Stcik, 150x2.2mm, small cotton head (5.5x12 mm)
	1101277	Applicator with wooden stick, 200x2.5mm, small cotton head, sterile
	1101400	Applicator with wooden stick, 150x2.2mm, small cotton head
	1102241	Applicator With Wooden Stick, 150x2.2mm, small cotton head
	1102242	Applicator With Wooden Stick, 150x2.2mm, small cotton head

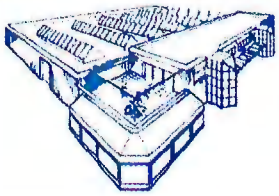
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1102245	Applicator With wooden stick, 150x2.2mm, small cotton head
1102246	Applicator with Wooden Stick, 150x2.2mm, small cotton head
1102248	Applicator with wooden Stick 150x2.2mm, small cotton head
1102257	Applicator with Wooden Stick, 150x2.2mm, small cotton head
1102267	Applicator with wooden stick, 150x2.2mm, small viscose head, sterile
1102269	Applicator with wooden stick 150x2.2mm, small cotton head, sterile
1102271	Applicator with wooden stick 150x2.2mm, small cotton head, sterile
1102274	Applicator with wooden stick 150x2.2mm, small cotton head, sterile
1102455	Applicator with Wooden Stick, 150x2.2mm, small cotton head
1106204	Applicator with wooden stick 150x2.2mm, small cotton head
1111405	Applicator with wooden stick, 150x2.5mm, medium cotton head, sterile
1111412	Applicator with wooden stick, 150x2.5mm, medium cotton head, sterile
1111413	Applicator with Wooden Stick, 150x2.5mm, Medium cotton head
1111414	Applicator with wooden stick, 150x2.5mm, medium cotton head (diameter 7-8mm)
1121243	Applicator with wooden stick,150x2.5mm, big cotton head, continental shape
1121244	Applicator with wooden stick, 150x2.5mm, big cotton head, continental shape, sterile
1121403	Applicator with wooden stick, 150x2.5mm, big cotton head, sterile
1121463	Applicator with wooden stick, 150x2.8mm, big cotton head, American shape, sterile
1121467	Applicator with wooden 150x2.5mm, big cotton head, American shape
1121469	Applicator with Wooden Stick, 146x2.8mm, big cotton head, continental shape
1121473	Applicator with wooden stick, 150x2.8mm, big cotton head, continental shape, sterile
1121475	Applicator with wooden stick, 150x2.8mm, big cotton head, American shape, sterile
1131461	Applicator with Wooden stick, 200x3mm, mega cotton head, American shape



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	1131466	Applicator with wooden stick, 200x3mm, mega cotton head (D=13mm), American shape
	1131563	Applicator with Wooden stick, 200x3mm, mega cotton head, Continental shape