

**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.

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

- are manufactured by **Applimed SA**,
- are Sterile Medical Devices
- are Medical Devices of Class Is rule 4
- 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 11<sup>th</sup> April 2021 until the 10<sup>th</sup> April 2024. Recertification audit due before 12 February 2024.

Basic UDI-DI: 0764017844SComCom0UN

Authorised Representative: Dansu A/S

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

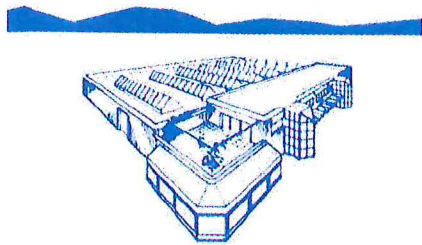
SRN: Not yet available.

Name: MOTTER, Giancarlo

Function: Regulatory Affairs Manager (PRRC)

Place: Châtel-St-Denis

Date: 11.06.2021



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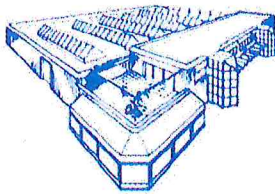
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Group	Article N°	Product/Family name
Abdo Compress	4502026	Abdo Compress with RX and Lace, 40x40 cm, 8 layer, double packaging
	4502027	Abdo Compress with RX and Lace, 50x50 cm, 8 layer, double packaging
	4502055	Abdo Compress with RX, 45x45 cm, 6 layers, double packaging
	4502056	Abdo Compress with RX and Lace, 45x45 cm, double packaging
	4502059	Abdo Compress with RX, 45x45 cm, 6 layers, double packaging
	4502073	Abdo Compress with RX and lace, 50x60 cm, 4 layers, double packaging With Crepe paper, 60x60cm
	4502093	Abdo Compress with RX and Lace, 50x60 cm, 4 layers double packaging
Cellulose Compress	4102010	Cellulose Compress, 4x5 cm
Cotton	4102015	Cotton, size : 20x17 cm, 15gr
Cotton Ball	4801129	Cotton ball, 0.7 gr
Non-Woven Ball	4101100	Non-Woven Ball, diameter 4.5 cm, double packaging
	4102265	Non-Woven Ball, diameter 4.5 cm, double packaging
	4102313	Non-Woven Ball, diameter 3-4cm, double packaging without RX
Non-Woven Compress	4502033	Non-Woven Compress, 7.5x7.5 cm, 40g
	4801113	Non-Woven Compress, 10x10 cm, 40 gr, precut in circle
	4801114	Non-Woven Compress, 5x5 cm, 40 gr, precut in circle
	4801132	Non-Woven Compress, 5x5 cm, 4 plies. 40gr, cut in "Y"
	4801150	Non-Woven Compress, 10x10 cm, 4 plies. 40gr
	4801810	Non-Woven Compress, 10x10 cm, 40g, 4 plies
	4802203	Non-Woven Compress, 5x5 cm, 40 gr, 4 plies
	4802206	Non-Woven Compress, 10x10 cm, 40g, 4 plies, double packaging
	4802209	Non-Woven Compress, 10x10 cm, 40 gr, 4 plies
Ophtalmic Compress	4908830	Ophtalmic Compress
Woven Ball	4101098	Woven Ball, diameter 2.5-3 cm
	4101102	Woven Ball, 8 cm, double packaging With 2 traceability labels



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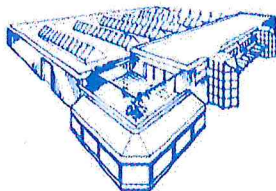
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	4102002	Woven Ball, diameter 2.5 cm
	4102008	Woven Ball, diameter 2.5/3 cm
	4102011	Woven Ball, diameter 7 cm
	4102264	Woven Ball, diameter 4.5 cm, double packaging
	4102300	Woven Ball, diameter 3 cm, double packaging
	4802212	Woven Ball, diameter 4-4.5 cm, simple packaging
Woven Ball RX	4102017	Woven Ball with RX, diameter 3 cm, double packaging
	4102263	Woven Ball with RX, diameter 4-4.5cm cm, double packaging
	4102266	Woven Ball with RX, diameter 3 cm, double packaging
	4102312	Woven Ball with RX, diameter 3 cm, double packaging
	4802118	Woven Ball with RX, diameter 3 cm, double packaging
Woven Bandage	7007060	Woven gauze bandage 24 threads 1cmx10m, folded
	7007061	Woven gauze bandage 24 threads 2cmx10m, folded
	7007062	Woven gauze bandage 24 threads 1cmx50cm, folded
	7007063	Woven gauze bandage 24 threads 2cmx90cm, folded,
Woven Compress	4501989	Woven Compress, 10x20cm, 24 layers, 17-20 wires
	4501992	Woven Compress, 10x10cm, 12 plies
	4502036	Woven Compress, 5x5cm, 12 layers
	4502037	Woven Compress, 10x10cm, 8 plies
	4502038	Woven Compress, 10x20cm, 24 layers, 17 wires, double packaging
	4502039	Woven Compress, 10x20cm, 24 plies, double packaging
	4502043	Woven Compress, 10x10cm, 16 plies, double packaging
	4502044	Woven Compress, 7.5x7.5cm, 12 layers
	4502045	Woven Compress, 10x10cm, 16 layers
	4502047	Woven Compress, 5x5cm, 12 plies, double packaging
	4502054	Woven Compress, 10x10cm, 16 layers
	4502077	Woven Compress, 10x20cm, 12 layers, 17 wires



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	4502079	Woven Compress, 10x10cm, 12 layers, double packaging
	4502092	Woven Compress, 10x20cm, 12 plies, double packaging
	4606208	Woven Compress, 5x5cm, 8 layers, 17 wires
	4606209	Woven Compress, 5x5cm, 12 layers, 17 wires
	4606210	Woven Compress, 10x10cm, 8 layers, 17 wires
	4606212	Woven Compress, 10x20cm, 12 layers, 17 wires
	4801126	Woven Compress, 5x5cm 2 Woven Compress, 5x5cm with incision 25mm
	4801127	Woven Compress, 7.5x10cm, pre-cut in "I"
	4901893	Woven Compress, 10x10cm
	4908835	Woven Compress, Moustache
Woven Compress with RX	4502001	Woven Compress with RX, 10x10cm, 12 layers, 17 wires, Double packaging
	4502031	Woven Compress with RX, 10x20cm, 24 layers, Double packaging
	4502041	Woven Compress with RX, 10x20cm, 24 layers, Double packaging
	4502068	Woven Compress with RX, 10x20cm, 24 layers, Double packaging
	4502075	Woven Compress with RX, 10x100cm, Double packaging
Woven Gauze Ball	4102009	Woven gauze ball, diameter 7-8 cm, without RX
Woven Puce Swab RX	4101103	Woven Puce Swab with RX, Size : M, double packaging
	4101104	Woven Puce Swab with RX, diameter 4-5 cm, double packaging
	4101105	Woven Puce Swab with RX, Size : L, double packaging
	4101140	Woven Puce Swab with RX, 4x4 cm, double packaging
	4102160	Woven Puce Swab with RX, size : L, double packaging
	4102161	Woven Puce Swab with RX, Size : M, double packaging
	4102310	Woven Puce Swab with RX, size : XS, double packaging
	4102311	Woven Puce Swab with RX, Size : S, double packaging