

BUREAU VERITAS
Certification



DIDACTIC S.A.S.

Certified site:

1800 Route des bleuets Le Mirlibut - 76430 Etainhus France

Bureau Veritas Italia S.p.A. certifies that the Production Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of

DIRECTIVE 93/42/EEC

(according to Annex V)

In relation to the following products

Product subcategory :	See Annex
Generic group:	See Annex
Model:	See Annex
Class:	See Annex

(may refer to the Annex of the certificate that lists all the products / models of devices subject to certification)

Reference BV practice: ZIG. N. 9407763

Original cycle start date: **01 May 1998**

Expiry date of previous cycle: **04 May 2019**

Certification / Recertification Audit date: **3 October 2018**

Certification / Recertification cycle start date: **12 April 2019**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **04 May 2024**

Certificate No. - Version: IT264816 - 2

Revision date: **21 May 2021**

GIORGIO LANZAFAME Local Technical Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza, 347-20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation. To check this certificate validity please refer to the website www.bureauveritas.it



Annex to the CE Certificate n° IT264816

Product subcategory :	Non-active instruments	
Generic group:	Sterile gloves	
Model:	Gynecological gloves	MG-5091
	Sterile examination vinyl powder-free gloves	MV-2201
	Sterile examination vinyl gloves	GVSNP-
Generic group:	Sterile stoppers	
Model:	Male and female stoppers	OBT-
	PE stoppers	OBTM-PE
Class:	Is	
Generic group:	Sterile Stopcocks	
Model:	Vas 3-way stopcocks	R3LVCR3
Class:	IIa	
Generic group:	Sterile Umbilical cord clamp	
Model:	CLAB	
Generic group:	Sterile finger cots	
Model:	MJD2210	

Note: the _ value following the initial reference can be replaced by an alpha - numeric value that completes the codification of an item to indicate a non-significant variation of the certified based model.

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Generic group:	Sterile Male and Female connectors
Model:	RACDLL-
Class:	Ila
Generic group:	Sterile safety pins
Model:	EPIS-
Class:	Is
Generic group:	Sterile valves
Model:	VAL-
Generic group:	Sterile oncology lines
Model:	LA-; LR-; SYST-
Product subcategory :	Non-active devices for injection, infusion, transfusion and dialysis
Generic group:	Sterile Aeration cannula
Model:	PRIA-
Class:	Is
Generic group:	Sterile Spikes
Model:	SPIK-
Class:	Ila

Note: the _ value following the initial reference can be replaced by an alpha - numeric value that completes the codification of an item to indicate a non-significant variation of the certified based model.

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