

**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 Full Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of*

### **DIRECTIVE 93/42/EEC**

*(in accordance with Annex II - excluding paragraph 4)*

*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: IT264815 - 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](http://www.bureauveritas.it)



## Annex to the CE Certificate n° IT264815

Product subcategory :	Non-active devices for injection, infusion, transfusion and dialysis	
Generic group:	Sterile infusion sets	
Model:	1-way infusion sets	PER1-
	3-way infusion sets	PER3-
	Multi-way infusion sets	PER-
	Infusion sets for photosensitive products	PERPP-
	Paediatric infusion set	PERP150F
	Specific infusion sets	PERSML-; PERY-

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

Reference BV practice: ZIG. N. **9407763**

Original cycle start date: **12 April 2019**

Expiry date of previous cycle: **04 November 2018**

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

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## Annex to the CE Certificate n° IT264815

Generic group:	Sterile extension lines	
Model:	Extension lines with rotating flow regulator	PMFLV-
	Extension lines with 3-way stopcocks	PR3LV-
	Male female extension lines	PMF-
	Male female extension lines for syringe pump	PMF-PS-
	Specific extension lines	PMFDYF-
	Extension lines for photosensitive product	PMFTJPS-
	Tri-layer extension lines for syringe pump	PMF-TPSA-
Generic group:	Sterile Administration sets for gravity transfusion	
Model:	TRA-	
Class:	IIa	

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

Reference BV practice: ZIG. N. 9407763

Original cycle start date: **12 April 2019**

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