

BUREAU VERITAS
Certification



CE Certificate

Issued to

ZAMAR D.O.O.

Head office and operative site:
SV. MARTIN, 6 - 52450 - VRSAR (PU) - CROATIA

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 as amended

(in accordance with Annex II - excluding paragraph 4)

In relation to the following products

Product type:	Biopsy needles and kits
Model:	See the annex
Class:	Ila

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

Reference BV practice: ZIG. N. 60482418

Certification cycle start date: **14 September 2016**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **13 September 2019**

Original certification date: **30 September 2014**

Certificate N. **IT257278**

Rev. N. 2 of: 14 September 2016


ANDREA FILIPPI - Local Technical Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Via Miramare, 15 - 20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370

Annex CE Certificate IT257278

Product Family:	Biopsy needles and kits	
Products/models:	Bone marrow biopsy and bone marrow aspiration	BPxx-xx, STxx-xx, ITxx-xx, ITAxx-xx, CSxx-xx.
	Needles for explantation	ITX-xx-xx, BPExx-xx, STExx-xx.
	Biopsy needles for automatic devices	RBxx-xx.
	Aspiration infusion needles for soft tissue and prenatal diagnosis	KV-xx-xx, KALxx-xx, KASxx-xx, KCCxx-xx, CNxx-xx, CNAxx-xx, CXxx-xx.
	Micro-histological and cytological biopsy of soft tissue	Hmxx-xx, HSxx-xx, HExx-xx, FExx-xx, WTxx-xx.
	Tissues localization	ELxx-xx, ELXxx-xx.
	Histological biopsy of soft tissues	PMxx-xx, PMOxx-xx, PXxx-xx, GSxx-xx, GSOxx-xx, GSBxx-xx, RCxx-xx, RCVxx-xx, RBxx-xx.
	Galactography	GKTxx-xx, GLCDxx-xx, GLSDxx-xx.
	Drainages	BGSETxx-xx, PKSETxx, TPSxx-xx, PCSxx-xx.
Notes: xx-xx with the first two variables is defined the "gauge" product for the size of the external diameters of needles, while the second two letters variables is defined useful length needle.		

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