

DECLARATION OF CONFORMITY

We
ZAMAR d.o.o.
Sv. Martin, 6 52450 Vrsar (PU) - Croatia
OIB 32940535452

Declare under our sole responsibility that medical devices products

BIOPSY NEEDLES AND KIT

Bone marrow biopsy and bone marrow aspiration	BPxx-xx (Cortex), STxx-xx (Selective), ITxx-xx (Selective Ily Type), ITAxx-xx (Selective Erg Type), CSxx-xx (Catch System);
Needles for explanation	ITXxx-xx (Selective E Ily Type), BPExx-xx (Selective E P Type), STExx-xx (Selective E);
Biopsy needles for automatic devices	RBxx-xx (Recharge Type);
Aspiration infusion needle for soft tissue and prenatal diagnosis	KVxx-xx (Chorial Villi), KALxx-xx (Amniocentesis Kit-Linear Type), KASxx-xx (Amniocentesis Kit-One Hand Use), KCCxx-xx (Funiculus Centesis Kit), CNxx-xx (Chiba), CNAxx-xx (Scout), CXxx-xx (Coaxial Needle);
Micro-histological and cytological biopsy of soft tissue	HMxx-xx (Hepamod), HSxx-xx (Hepatek), HExx-xx (Hepasys), FExx-xx (Franseen), WTxx-xx (Westcott);
Tissue localization	ELxx-xx (Easyloc), ELXxx-xx (Easyloc)
Histological biopsy of soft tissue	PMxx-xx (Ultimate), PMOxx-xx (Ultimate), PXxx-xx (Ultimate Set), GSxx-xx (Vantage), GSOxx-xx (Vantage), GSBxx-xx (Vantage B type), RCxx-xx (Recharge), RCVxx-xx (Recharge V Type), RBxx-xx (Recharge Type);
Galactography	GKTxx-xx (Galattok), GLCDxx-xx (Galattok), GLSDxx-xx (Galattok)
Drainages	BGSETxx-xx (BGSET), PKSETxx (PKSET), TPSxx-xx (TPS), PCSxx-xx (PCS).
Note: the 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 for useful length needle.	

To which this declaration relates, have been designed and manufactured in accordance with the requirements of Directive 93/42/EEC and subsequent amendments

Class IIa Medical Devices

Certificate No. IT257278 - 1

so CE mark is affixed with identification number 1370.

Vrsar, li 10/09/2019

Executive Manager
Gianmarco Zanotti

ZAMAR d.o.o.
Poreč