



F.L. MEDICAL s.r.l. Unipersonale
Via Enrico Mattei, 20 – 35038 TORREGLIA (Padova) – Italy
Tel. +39 049 5211475 / +39 049 5212835 - Fax +39 049 5212566
e-mail: info@flmedical.com - web site: www.flmedical.com
C.F. e P.IVA 01134840287 - Cap Soc. 90.000 € i.v.
Reg. Imp. di Padova n. 21695 - R.E.A. di Padova n. 187254

TO WHOM IT MAY CONCERN

F.L. MEDICAL s.r.l.

Having headquarters in

Via Enrico Mattei, 20
35038 TORREGLIA (PADOVA)
ITALY

Manufacturer of disposable labware for laboratory analysis

declares that

Vacumed Blood collecting Needles are medical devices of class IIa following the European Medical Devices directive MDD 93/42/ECC. They are CE marked following the conformity assessment procedure set out in annex II of the Medical Device Directive. The related certificate has been issued by the Notified Body N° 17752 Certiquality.

Vacumed Blood collecting Needles are sterilized following a validated sterilization method and released in routine in accordance with the requirements specified in EN ISO 11135 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices". The products are in compliance with the requirements regarding sterility specified in EN-556_1 "Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Requirements for terminally sterilized medical devices".

Vacumed Blood collecting Needles are intended for single use and are available for multiple sampling.

The geometry of the needle point of the Vacumed Blood collecting Needles complies with EN ISO 7864 "Sterile hypodermic needles for single use".

The Vacumed Blood collecting Needles are colour coded in accordance with the specification of ISO 6009 "Hypodermic needles for single use -- Colour coding for identification.

Torreglia, 28.11.2014

F.L. Medical s.r.l.
Alessandro Fiore
(Quality control)

A handwritten signature in black ink, appearing to be 'Alessandro Fiore', written in a cursive style.