DECLARATION OF CONFORMITY



The manufacturer:

Neatech.it

Via A. de Curtis 4/A, 80040, Cercola (NA), Italy – VAT ID IT04812481218

declares that:

the product LB (reference code: S080)

other names: LEVIA BASCULANTE - LEVIA KID - LEVIA BASCULANTE KID - LBK - LB DYNAMIC

- satisfies the requirements laid down by the European Directive 93/42/EEC;
- according to the criteria for classification of Annex IX of this Directive, it is classified as:

class I medical device;

• the satisfaction of requirements is evalued according Annex VII of European Directive 93/42/EEC and the product is in conformance with the following standards:

EN ISO 14971:2012,

EN 12182:2012,

EN 12183:2014:

• is designed and manufactured under a quality management system, certified to ISO 9001:2015 by the certification body TUV Italia s.r.l. certificate N° 50 100 13780-001.

I, the undersigned, hereby declare that the device specified above is compliant with European Directive 93/42/EEC.

Name:

Raffaele Grosso

Title:

CEO

On behalf of:

Neatech.it srl

Date:

2018-02-26

Signature: