DECLARATION OF CONFORMITY

CE

The manufacturer:

Neatech.it

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

declares that:

the product ANKLET
(reference code: T006_05)
other names: CAVIGLIERA

- 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 12182:2012,

- a risk analysis for the mentioned device was performed following indications of EN ISO 14971:2012;

  for the risk analysis, all possible options, variations and accessories described in the order form and in the manual were considered;

- 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.

Signed by:

Name:	Feliciano Ferraro
Title:	Quality assurance manager
On behalf of:	Neatech.it s.r.l.
Date:	2018-09-11

Signature:

NEATECH.IT s.r.l.
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