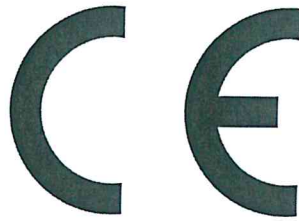


# DECLARATION OF CONFORMITY



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 evaluated 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.  
Via A. De Curtis, 4 - 80040 CERCOLA (NA)  
Tel. 081 5551946 - Fax 081 5552522  
