Notified Body n° 0426

ITALCERT

ITALCERT S.r.l.
viale Sarca, 336 - IT 20126 MILANO MI
tel. +39 0266104876 fax +39 0266101479
E-mail italcert@italcert.it

CERTIFICATE n° 237-01-00-DM

(in compliance with Annex II of the Directive 93/42/EEC)

ITALCERT

certifies that the

Full Quality Assurance System
applied for the design, manufacture and final inspection
of "Medical Devices" - MD -

by the manufacturer

BIOTECHWARE S.r.l.

Via Cardinal Massaia 83 – 10147 Torino (TO) - ITALY

in the headquarters located in

Via Cardinal Massaia 83
10147 Torino (TO) - ITALY

complies with the requirements stated in

Directive 93/42/EEC - Annex II (excluding point 4)

and authorizes the manufacturer to mark

CE 0426

in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC
the MD reported in Annex 1 of this Certificate

dr. ing. Roberto Cusolito
MANAGING DIRECTOR

First issue date	Current issue	Expire date
2013-11-18	2019-06-26	2023-11-17

This certificate must be published only in integral form and accompanied by its Annex 1
This certificate is the English translation of the certificate n° 237-01-00-DM issued by ITALCERT Srl in Italian language.
In case of discrepancy you must refer to the original certificate issued in Italian language.

ITALCERT S.r.l.
viale Sarca, 336 - IT 20126 MILANO MI
tel. +39 0266104876 - fax +39 0266101479
E- mail italcert@italcert.it
Notified Body n° 0426

Annex 1 to Certificate n° 237-01-00-DM

Active medical devices intended for diagnosis *(class IIa)*

- Device intended to detect and record the heart's electrical signal - ECG - *(CARDIOPAD PRO)*

Milan, 2019-06-26

dr. ing. Roberto Cusolito
Managing Director