



DECLARATION OF CONFORMITY

Device: **BIA101 BIVA**

Manufacturer: Akern S.r.l.

Registered Office: Via Umberto Forti 6 - 56121 frazione Montacchiello, Pisa (PI), Italy

Operational Site: Via Lisbona 32/34 - 50065 Pontassieve (Florence, Italy)

Authorised representative: Yann Inghilesi Gialloni

Compliance with **Directive 93/42/EEC** as amended for Medical Devices, Class IIa, is obtained by means of a product certification procedure in accordance with annex II (not including point 4), and the device is manufactured in accordance with the technical documentation required by point 3 of annex VII.

Notified Body

BUREAU VERITAS ITALIA S.p.A.

Viale Monza, 347

20126 Milan - Italy

Conformity marking



YANN INGHILESI GIALLONI
Chief Executive Officer Akern S.r.l.
