

DECLARATION OF CONFORMITY

Manufacturer

SCHILLER AG
Altgasse 68
6341 Baar

Worldwide exclusively distributed by:

ESAOTE S.p.A.
Via di Caciolle 15
50127 - FLORENCE
ITALY

Product

Electrocardiograph

Type

P80 Serial numbers starting with: 9740400010 00100ff / 9740400011 40000ff
9740400040 80000ff / 9740400041 90000ff
9740400021 60000ff / 9740400020 20000ff

We, the undersigned, hereby declare that the medical device (class II a) specified above conforms with the Essential Requirements listed in Annex I, of EC Directive 93/42/EEC.

The appendix II of the Directive 93/42/EEC from June 1993 is being applicable.

Applied standards:

IEC 60601-1
IEC 60601-1-2
IEC 60601-2-25



Baar (Switzerland), 08.04.2008

Sym.

Sezer Serkan
Quality Assurance & Regulatory Affairs Manager

