11. Declaration of Conformity

EC Declaration of Conformity

We hereby declare under our sole responsibility that the product

OXYTRUE® A,

HANDHELD PULSE OXIMETER FOR CONTINUOUS AND SPOT-CHECK MONITORING OF FUNCTIONAL ARTERIAL OXYGEN SATURATION (SPO2) AND PULSE RATE,

PRODUCT No. 1020112001

conforms with the essential requirements of Annex I of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

In accordance with Annex IX of the Directive 93/42/EEC the product has been classified as Class IIb.

Application of the CE-marking:



Issuer:

bluepoint medical GmbH & Co. KG An der Trave 15 D-23923 Selmsdorf Germany

Place, Date:

Selmsdorf, 12/ Nov/ 2007

Legally binding signature:

Bernd Lindner (Managing Director)