PHARMALAB
INTERNATIONAL

Declaration of Conformity

Manufacturer
Name:
Address:
Tel:
Website:

European authorized Representative
Name: Prolinx GmbH
Address: Brehmstr. 56, 40239, Duesseldorf, Germany

Product: Pulse Oximeter

Type: BM1000C, BM1000D
Classification (MDD, Annex Ⅸ): **Ⅱb, Rule 10**
We herewith declare under our sole responsibility that the abovementioned products meet transposition into national law, the provisions of the following EC Council Directives and Standards. The manufacturer is exclusively responsible for the Declaration of Conformity.
The oximeter is complied with the standard ISO80601-2-61.

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC amended by 2007/47/EC concerning medical devices (MDD 93/42/EEC).

Approach of application: According to MDD 93/42/EEC evaluation procedures and certificate confirmation, the approach of application of product authentication is **Annex Ⅱ without section 4**.
Notified Body: TüV SüD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
NB identification number: 0123
EC Certificate: