



**BPC BioSed S.r.l.**

Offices, Laboratories and Warehouse  
Area Industriale - Traversa del Grillo km0,600  
00060 Castelnuovo di Porto Rome / ITALY  
Tel.: +39 06 9073666 - Fax: +39 06 9073200



## DECLARATION OF CONFORMITY



*BPC BioSed S.r.l. declares and warrants, under its own responsibility, that the product: KEYLAB*

<b>REF.: 16-0000</b>	<b>DESCRIPTION : KEYLAB</b>
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With the serial number


XXXXXXXXXXXXXXXXXXXXXX

Conform to the essential requirements – Enclosure I of Law Decree 332/00 “ Actuation of Directive 98/79/CE related to medical diagnostics In Vitro” and to the reference norms:

- EN 14971                      Medical Devices – Application of risks management to medical devices.
- EN 980                        Graphic Symbols used for labelling of medical devices.
- EN 591                        Operative Instruments of In Vitro Diagnostic instrumentation for professional use.
- CEI EN 61010-2-101        Safety prescriptions for electrical devices for measure, control and for use in laboratory.  
Part 2-101: Particular prescriptions for medical devices and In Vitro Diagnostic (IVD).
- EN 61326/A1                Electrical appliances for measure, control and laboratory, prescriptions of Electro-Magnetic compatibility.
- 2006/95/CE                 Concerning the approximation of the member state legislations related to the electric material destined to be used within certain tension limits.
- 2004/108/CE                Directive on the electromagnetic compatibility detailed with law decree 194/07 realization of directive 2004/108/CE concerning the approximation of the member states legislation related to the electromagnetic compatibility and that repeals the directive 89/336/CEE.

BPC BioSed S.r.l. declares moreover that:  
The product doesn't belong to the Enclosure II Lists A and B neither it is a self diagnosis test and is not used for evaluation of performances.

DATE: February 10<sup>th</sup> 2007

  
 Franca MARTINELLI  
 Managing Director  
 BPC BioSed S.r.l.