BPC BioSed Srl
00060 Castelnuovo di Porto - ROME/ITALY - Traversa del Grillo km. 0,600
Phone: +39 069073666 - Fax: +39 069073200
www.bpcbiosed.it - EMAIL: info@bpcbiosed.it
Cap. Soc. 98.800,00 i.v. - Cod Fisc. 07732700583 - P. IVA IT01854651005 - C.C.I.A.A. Roma n. 627092 - Reg. Soc. Trib. RM 923/87

DECLARATION OF CONFORMITY

CE

BPC BioSed S.r.l.

declares and warrants, under its own responsibility, that the products listed below

REF: 22-0000	**Description: GLOBAL 4500DR Automated Biochemistry Analyzer**

and its equivalent variant:

REF: 22-G7500DR	**Description: GLOBAL 7500DR Automated Biochemistry Analyzer**

are in conformity with

the **European Directive 98/79/CE**

These products are self-certified since they are for professional use only and are not listed on Annex II, List A and B of European Directive 98/79/CE; furthermore, they are not self-diagnosis tests and they are not used for evaluation of performances.

These devices fulfil the relevant essential requirements set out in Annex I of Law Decree 332/00 "Actuation of European Directive 98/79/CE related to medical diagnostics In Vitro" in view of their intended use.

These products also apply the following Standards and sector Directives:

UNI EN ISO 9001:2015	**Quality management system-Requirements**
ISO 13485:2016	**Medical Devices- Quality management systems- Requirements for regulatory purposes**
Directive 2012/19/UE	**On waste electrical and electronic equipment**
Directive 2011/65/UE	**On the restriction of the use of certain hazardous substances in electrical and electronic equipment**
Directive 2014/35/UE	**On the harmonisation of the laws of the Member States relating to making available on the market of electrical equipment designed for use within certain voltage limits**
Directive 2014/30/UE	**On the harmonisation of the laws of the Member States relating to electromagnetic compatibility**

Jean-François Charpentier
Managing Director
BPC BioSed S.r.l.