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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.

These products also apply the following Standards and sector Directives:

UNI EN ISO 9001	**Quality management system-Requirements**
ISO 13485	**Medical Devices- Quality management systems- Requirements for regulatory purposes**
UNI CEI EN ISO 14971	**Application of risks management to medical devices**
CEI 62304	**Medical device software-Software life cycle processes**
Directive 93/42/CE	**Concerning Medical Devices**
UNI EN ISO 18113-1/-3	**IVD-Information supplied by the manufacturer (labelling)**
Directive 2006-42-CE	**The Machinery Directive**
Directive 2002/96/CE	**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**
CEI 60601-1-2/-1-6/-1-8	**Medical electrical equipment- General requirements for basic safety and essential performance**
UNI EN ISO 15223-1/-2	**Symbols to be used with medical device labels, labelling and information to be supplied**
CEI EN 61010-1/-2-101	**Safety requirements for electrical devices for measurement, control and laboratory use- in particular for IVD**
CEI 61326-2-6	**Electrical equipment for measurement, control and laboratory use- Particular requirements for IVD**
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.

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