



DECLARATION OF CONFORMITY



BPC BioSed S.r.l.

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

REF: 19-0000	Description: GLOBAL 240 Automated Biochemistry Analyzer
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and its equivalent variant:

REF: 19-G720	Description: GLOBAL 720 Automated Biochemistry Analyzer
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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