



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; 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
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 BPC BioSed S.r.l.