Abbott

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DECLARATION OF CONFORMITY

AFINION™ 2

We hereby declare that Afinion™ 2 Analyzer is in conformity with the following directives:

- Directive 98/79/EC of the European Parliament and of the Council on *In Vitro* Diagnostic Medical Devices.
- Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2).

Global Medical Device Nomenclature (GMDN):
[56681] Point-of-care single channel clinical chemistry analyser IVD

Legal Manufacturer:	**Abbott Diagnostics Technologies AS**
Address:	Kjelsåsveien 161 P.O. Box 6863 Rodeløkka NO-0504 Oslo, Norway

Package variants covered by this certificate:

Product name	Catalogue No. (REF)	Package variant
Afinion™ 2	1116770/1116771	Standard
Afinion™ 2	1116777/1116778	NOR
Afinion™ 2	1116772	IN

This *in vitro* diagnostic medical device complies with all applicable Essential Requirements as set out in Annex I of Directive 98/79/EC. Technical documentation is established according to the requirements in Annex III of Directive 98/79/EC.

Afinion™ 2 Analyzer is an IVD medical device intended for professional point-of-care use. According to Directive 98/79/EC intervention by a Notified Body is not required since the product is classified as a general/common *in vitro* diagnostic medical device (it is not covered by Annex II List A or B and it is not a device for self-testing).

Monica Vallestad
Regulatory Affairs Manager
Abbott Diagnostics Technologies AS

2019-02-26
Date (yyyy-mm-dd)

Abbott Diagnostics Technologies AS