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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

Manufacturer: **Alere 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	1116679/1116680	Standard
Afinion™ 2	1116682/1116684	NOR
Afinion™ 2	1116558	JP
Afinion™ 2	1116681	IN
Afinion™ 2	1116554/1116663	US

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).

8 February 2018
Date

Eldri Prestegård
Regulatory Affairs Manager
Alere Technologies AS

Alere Technologies AS