Abbott

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DECLARATION OF CONFORMITY
NycoCard™ CRP

We hereby declare that NycoCard™ CRP is in conformity with Directive 98/79/EC of the European Parliament and of the Council on *In Vitro* Diagnostic Medical Devices.

Global Medical Device Nomenclature (GMDN): [53707] C-reactive protein (CRP) IVD, reagent

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
NycoCard™ CRP	1116807	48 tests, Standard
NycoCard™ CRP	1116807	48 tests, 1116808 (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.

NycoCard™ CRP 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).

Eldri Prestegård

Eldri Prestegård
Regulatory Affairs Manager
Abbott Diagnostics Technologies AS

2020-01-06

Date (yyyy-mm-dd)

Abbott Diagnostics Technologies AS