EU DECLARATION OF CONFORMITY

For the In Vitro Medical Device:

CardiNor Secretoneurin ELISA assay, product number 100-01

Legal manufacturer of the CardiNor Secretoneurin ELISA Assay is:

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The CardiNor Secretoneurin ELISA Assay is an in vitro diagnostic medical device classified as General IVD according to Annex III of the IVD-directive and considered a low-risk product.

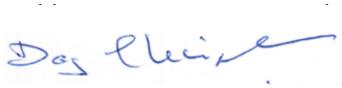
We, CardiNor AS, hereby declare that the CardiNor Secretoneurin ELISA assay, subject to CE marking according to the EU Directive 98/79/EC on IVDs, meets the applicable provision in the directive.

The following harmonized standards have been applied:

Code	**Document title**
EN ISO 13485:2016	Medical Device – Quality management systems – Requirements for regulatory purposes.
ISO 14971:2019	Medical Device – Application of risk management to medical devices.
NS-EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general.
NS-EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

NS EN ISO 15223_1:2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2012).
ISO 23640:2011	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagent.
EN 13612:2002	Performance evaluation of in vitro diagnostic medical device.
BS EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices. Statistical aspects.

Oslo, December 22, 2021



Dag Christiansen
CEO
CardiNor AS