



EC Declaration of Conformity (EN)

We, the legal manufacturer, as stated below hereby declares under our sole responsibility,

Legal Manufacturer	EMBIO Diagnostics LTD.
Address	Athalassas avenue 8B, Nicosia, Cyprus, 2018 Tel: +357 22 515 175 Web: embiodiagnostics.eu Email: info@embiodiagnostics.eu

That the identified product to which this declaration relates,

Identification	
Product Name	CovBELD
Catalogue Number	CovBELDv3.1_10xx
Classification	General IVD and associated software – as referred to by Article 9, §1 of 98/79/EC
Conformity Assessment Route	Annex III (excluding section 6) of 98/79/EC

Is in conformity with the following European Regulations and Directive as transposed into the national laws of the member states:

Directives and Regulations
Directive 98/79/EC of the European parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Signed for and on the behalf of Manufacturer SK EMBIO DIAGNOSTICS LTD:

Name	Constantinos Loizou
Position	C.E.O
Signature	
Date	24/11/2020

With approval of this Declaration of Conformity, we hereby affix the CE Mark to the product CovBELD (CE mark applies to BELD Device and associated software, Disposable electrodes and biosensor).