Documentnummer 20201231

Directlab B.V.
Hofstede 5
2821 VX Stolwijk
T 085 3031599

Declaration of conformity

medical devices

We hereby declare that the distributed CE marked products, specified in the annexed product list, conform to the required technical documentation, in accordance with Annex III of the "EC-Directive", the Council Directive 98/79/EC of 27 October 1998, concerning in vitro diagnostic medical devices.

Directlab PRO Blood Collecting Kit
Directlab Professionele bloedafnameset

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directive which apply to them.

This Declaration of Conformity covers (product family name) as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site(s):

M. Lasschuyt
Directeur Directlab B.V.

05-01-2021 — Date
Gouda — Place

K. Wisser
Directeur Directlab B.V.

31-12-2020 — Date
Gouda — Place

Annex to the Declaration of Conformity (Product list)

Products listed under this declaration of conformity

Productnaam	**Batch nummer**
Directlab Pro bloedafnameset	First batch number 001PSPO2021 produced under this DoC