EC Declaration of Conformity

We hereby declare under our sole responsibility that the product

AlcoTrue M Alcohol Breath Analyzer

REF Number 5040112002

Conforms with the essential requirements of Annex I, Annex V and Annex VII of the Council Directive 93/42/EEC as amended by 2007/47/EC concerning medical devices as well as the requirements of Regulation (EU) 2017/745, Article 120, Chapter (3).

In accordance with Annex IX of the Council Directive 93/42/EEC the product has been classified as Class I with measurement function.

Application of the CE-marking:



DNV MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg, Germany

Validity: Date of expiry: 31 January 2026

Issuer: bluepoint medical GmbH & Co. KG

An der Trave 15 23923 Selmsdorf

Germany

Place, Date: Selmsdorf, 31 January 2025

Legally binding signature:

Bernd Lindner General Manager