

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, Brooktorkai 18, 20457 Hamburg, Germany

Validity:

Date of expiry: 31 December 2028

Issuer:

bluepoint medical GmbH & Co. KG
An der Trave 15
23923 Selmsdorf
Germany

Place, Date: Selmsdorf, 31 January 2026

Legally binding signature:



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Bernd Lindner
General Manager