

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

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

has introduced and maintains a quality assurance system
concerning the conformity of the medical devices with the metrological requirements

for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the
Council Directive 93/42/EEC was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

This certificate is valid until 02 November 2023

Report No.: 4026FS15F
Process No.: QS – 4026
Certificate No.: 4026GB416190712

Hamburg, 12 July 2019

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010014e EN / Rev. 8 / 2019.05.22



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 4026

Certificate No.: 4026GB416190712

List of products / product categories included in the scope of certificate**Medical breathalyzers**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010014e EN / Rev. 8 / 2019.05.22



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15