EU-Konformitätserklärung
EU-Declaration of Conformity

Dokument Nr. / *Document No.* *11139481-01*

Wir / *we* Dräger Safety AG & Co. KGaA, Revalstraße 1, 23560 Lübeck, Germany, SRN: DE-MF-000014172

erklären in alleiniger Verantwortung, dass das Medizinprodukt
declare under our sole responsibility that the medical product

Atemalkoholkonzentrationsmesser Alcotest 7000med
Breath-alcohol concentration measuring device Alcotest 7000med
REF/ *REF: 3700399*
BUDI-DI / *BUDI-DI: 04026056A7000medJP*

mit dem EG-Zertifikat gem. (EU) 2017/745 Anhang IX für Messfunktion **Reg. Nr.** *D146100005*
with the EC-Certificate acc. (EU) 2017/745 Annex IX for the aspect of the measuring function

ausgestellt von der notifizierten Stelle	**medical device certification**
mit der Kenn-Nr.	**Kriegerstr. 6**
issued by the Notified Body	**D-70191 Stuttgart**
with the Identification No.	**0483**

und mit den folgenden Richtlinien unter Anwendung der aufgeführten Normen übereinstimmt:
and is in compliance with the following directives by application of the listed standards:

Diese EU-Konformitätserklärung ist gültig bis zum: ***2027-12-14***
This EU-Declaration of Conformity is valid until:

Bestimmungen der Richtlinie *provisions of directive*		**Nummer sowie Ausgabedatum der Norm** *Number and date of issue of standard*
2017/745/EU	**Medizin Produkte-Verordnung MDR** *Medical Devices Regulation* **Klasse I mit Messfunktion (Klassifikation nach Regel 13)** *Class I with a measuring function (Classification due to rule 13)*	EN ISO 20417:2021, EN ISO 10993-1:2018-08, EN ISO 14971:2019, EN ISO 15223-1:2021, EN 60601-1:2006+Cor.2010 / A1:2013, EN 60601-1-2:2015, EN 62304:2006 +Cor.:2008 +A1:2015 EN ISO 62366 :2015/AC :2015
2014/53/EU	**RED-Richtlinie** *RE Directive*	EN 61326-1:2013 Immunity: Class A Emission: Class B EN 301 489-1 V2.2.3, EN 301 489-17 V3.1.1 EN 300 328 V2.2.2 EN 62479:2010 EN 62368-1:2014+AC:2015+A11:2017
2011/65/EU	**RoHS-Richtlinie** *RoHS Directive*	EN 50581:2012

Surveillance of Quality Assurance Production by (Category III, Module D)	**medical device certification** **Kriegerstr. 6** **D-70191 Stuttgart**
Certificate No.:	**0483**

Lübeck, 2023-01-03

Place and date (yyyy-mm-dd)

Dr. Marcus Romba
Head of Product Compliance
R&D Safety

Lübeck, 2023-01-03

Place and date (yyyy-mm-dd)

Robert Otta
PRRC Head of Quality Management & Quality Assurance

EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: DE-MF-000014172)

Dräger Safety AG & Co. KGaA

Revalstraße 1
23560 Lübeck
Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils the following requirements:

Annex IX - Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2022-12-15	Registration No.	D1486100005
Valid until:	2027-12-14	Evaluation Report No.	209748

Stuttgart, 2022-12-15

Head of Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Product: Dräger Alcotest 7000 med

Risk class: I (measuring function)

Notes:

For class I devices with a measuring function the involvement of mdc is limited to the assessment of the aspects relating to the conformity of the devices with the metrological requirements.