EU Declaration of Conformity

according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

Medical Device	AEC Chamber	
Product code (REF number) and Basic UDI-DI according to Part C of Annex VI	REF number	Basic UDI-DI
	140 00 13, 141 00 18, 141 00 20	++B851AECCHAMBERAFX
	142 00 13	++B851AECCHAMBERBFZ
	143 00 06	++B851AECCHAMBERCG3
	145 00 44, 145 00 97, 145 00 45	++B851AECCHAMBERDG5
	151 00 18, 151 00 21, 151 00 22	++B851AECCHAMBEREG7
EMDN code	Z110390	
Intended Purpose	The AEC chamber is an accessory for X-ray systems (projection radiography). The AEC chamber provides a signal proportional to the image receptor dose and, in conjunction with the AEC in the X-ray system, allows X-ray imaging with optimal diagnostic image quality with minimal patient radiation exposure. The AEC chamber is designed for continuous operation in professional health care facilities (clinics, hospitals, medical practices). The intended user and the intended patient are defined by the intended use of the X-ray system. There are no known contraindications or side effects.	
Classification according to Annex VIII	IIb according to rule 10 clause 2	

Manufacturer	VacuTec Meßtechnik GmbH Dornblüthstraße 14a 01277 Dresden Germany
Single Registration Number of manufacturer according to Article 31	DE-MF-000006432

We hereby declare, on our sole responsibility, the conformity of the abovementioned medical device(s) in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

We hereby ensure that the medical device(s) that is/are covered by the present declaration is/are in conformity with Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Applied Common Specifications (CS)

Common Specification(s)	none

VACUTEC

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Notified Body	TÜV Rheinland LGA Products GmbH ID of the Notified Body: CE 0197 Tillystraße 2 90431 Nürnberg
Conformity assessment procedure performed	Annex IX, Chapter I
Certificate(s) issued	EC Certificate Registration No.: HZ 1170821-1 valid until 2030-06-26
CE marking since	Since 03.2005 according to Directive 93/42/EWG Since 06.2025 according to Regulation (EU) 2017/745
EU Declaration of Conformity is valid for	Products placed on the market from 2025-06-26 valid until 2030-06-26

Signed on behalf of VacuTec Meßtechnik GmbH

Dr. Bettina Jakob	Dresden, 2025-09-01	
Executive Management	Place, Date	Signature

VACUTEC Meßtechnik GmbH
Dornblüthstr. 14a
01277 Dresden
Germany
www.vacutec-gmbh.de