



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	Dose / Dose Area Product Measuring System VacuDAP		
Product code (REF number), model and Basic UDI-DI according to Part C of Annex VI	REF number	Model	Basic UDI-DI
	156 00 07, 156 00 10, 157 00 10, 157 00 12, 157 00 15	VacuDAP 2004 OEM	++B851VACUDAP2004OEMZK
	156 00 13, 156 00 15, 156 00 18, 158 00 10, 158 00 12, 158 00 13, 158 00 15	VacuDAP - OEM	++B851VACUDAPOEMUX
	156 00 04, 156 00 05, 156 00 06, 158 00 05	VacuDAP compact	++B851VACUDAPCOMPACT42
	156 00 14, 158 00 14, 156 14+943 06, 156 14+943 61, 158 14+943 06, 158 14+943 61	VacuDAP Bluetooth®	++B851VACUDAPBLUETOOTH XH
	456 00 15, 458 00 15	VacuDAP - OEM duo	++B851VACUDAPOEMDUO8D
	159 01+922 22, 159 03+922 21 159 08+922 11, 159 12+922 16 159 13+922 24, 159 17+922 14 159 17+922 17, 159 28+922 28 159 76+922 75, 159 79+922 75 159 79+922 78, 160 01+922 13 160 03+922 27, 160 16+922 26 160 18+922 26	VacuDAP-C	++B851VACUDAPC55
	161 01+922 01, 161 02+922 02 161 02+922 29, 161 03+922 03 161 04+922 04, 161 17+922 05 161 19+922 05	VacuDAP-C duo	++B851VACUDAPCDUOBK
EMDN code	Z11039099		
Intended Purpose	The Dose / Dose Area Product Measuring System VacuDAP is an accessory for diagnostic X-ray equipment (radiography and radioscopy) and serves to monitor the patient dose in radiological applications. The Dose / Dose Area Product Measuring System VacuDAP is a secondary measuring device for determination of the dose area product, dose area product rate, irradiation time and optionally air kerma and air kerma rate at the reference point in patient radiological examinations. The values obtained are used for comparison with diagnostic reference levels for diagnostic and interventional X-ray applications. The display of the air kerma and air kerma rate at the reference point form the basis for calculating the skin dose during fluoroscopy. The Dose / Dose Area Product Measuring System VacuDAP is intended for continuous operation in professional health care units (clinics, hospitals, medical practices). The intended patient is defined by the intended use of the X-ray equipment. There are no known contraindications and side-effects. The Dose / Dose Area Product Measuring System VacuDAP must not be used to control the generator and must not be used for primary determination of characteristic data of X-ray equipment.		
Classification according to Annex VIII	Im (with measuring function) according to rule 13		



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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
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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 09.1998 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

