



JUR-EU-MDD-DOC

EU MDD Declaration of Conformity

CE- Declaration of Conformity

Accordinging Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Medical Device	Dose / Dose Area Product Measuring System VacuDAP in the following models: VacuDAP 2004 OEM, VacuDAP - OEM, VacuDAP - OEM <i>duo</i> , VacuDAP <i>duo</i> VacuDAP <i>standard</i> , VacuDAP <i>twin</i> , VacuDAP <i>fluoro</i> , VacuDAP <i>Bluetooth</i> [®] , VacuDAP <i>compact</i> , VacuDAP-C, VacuDAP-C <i>duo</i> , VacuDAP-C <i>Bluetooth</i> [®] , VacuDAP-C <i>Bluetooth</i> [®] <i>duo</i>
Classification	Class Im according to Council Directive 93/42/EEC Annex IX; Rule 12
UMDNS Code	11-295
GMDN Code	NA
Manufacturer	VacuTec Meßtechnik GmbH Dornblühstraße 14a 01277 Dresden Germany

We herewith declare under our sole responsibility the conformity of the above mentioned medical device with the Council Directive 93/42/EEC.

Selected conformity assessment procedure	According to Council Directive 93/42/EEC, Annex II, excl. section 4
Notified Body	TÜV Rheinland LGA Products GmbH ID of the Notified Body: CE 0197 Tillystraße 2 90431 Nürnberg
EC-Certificate	HD 60149031 0001 valid until 2024-05-26
CE-mark since	1999
SN	The declaration is valid for manufactured products starting with SN 2003998 in connection with manufacturing records.

Dresden, 2020-05-05

Dr. Wörmann, Bernd
General Manager