

# CE Uygunluk Beyanı / EU Declaration Of Conformity

**Üretici / Manufacturer:** ORUBA Medikal Teknoloji ARGE İç ve Dış Tic. Ltd. Şti.  
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**Ürün / Product:** OruFLOW v1.1 Self-Operating Uroflowmetry

**Sınıflandırma / Classification:** Class Iıa

**Standartlar / Standards:**

Number	Standards' Number	Name	Ver.
1	EN ISO 62304/A1	Medical device software – Software life-cycle processes	2009/2016
2	EN ISO 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	2015
3	EN ISO 60601-1/A12	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	2015
4	EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	2016
5	EN ISO 14971	Medical devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)	2013
6	EN 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	2016
7	EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes	2012
8	EN 1041 + A1	Information supplied by the manufacturer of medical devices	2011/2014
9	EN 60601-1-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	2007
10	93/42/EEC	Medical Devices Directive	2011
11	MEDDEV 2.7.1 Rev.3	Guidelines on Medical devices – Clinical evaluation	2009
12	MEDDEV 2.4.1 Rev.9	Medical devices: Guidance document – Classification of medical devices	2010
13	MEDDEV 2.12.1 Rev.8	Guidelines on a medical devices vigilance system	2013
13	2007/49/EC	COMMISSION DIRECTIVE	2007
14	MEDDEV 2.12/2 rev. 2	Post Market Clinical Follow-up	2014

**Onaylanmış Kuruluş / Notified Body:** UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. Ltd. Şti.  
Mutlukent Mah. 2073 Sk. No: 10 Ümitköy - Çankaya – ANKARA

**Onaylanmış Kuruluş Numarası / Notified Body Number:** 2292

**Sertifika Numarası / Certificate number:** M.2016.106.7384

**Yetkili İmza / Authorized Signature:**

Utku Uluşahin

Genel Müdür / General Manager

Ankara, 28/12/2016

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