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# DNV BUSINESS ASSURANCE

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## EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

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Certificate No. 6280-2015-CE-IND 0.0  
This Certificate consists of 3 pages

*This is to certify that the Quality Management System of*

### **BioTech Ophthalmics Pvt. Ltd.**

Plot no. 555, 556, 557 Khatraj-Vadsar Road, Opp. Subham Tex-O-Pack, Village Khatraj, Tal. Kalol, Dist. Gandhinagar, Gujarat, India

*for design, production and final product inspection/testing of*

### Solutions for Urology Use

*has been assessed with respect to*  
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

*Further details are given overleaf*

*Place and date:*

Høvik, 13 April 2015

For DNV GL BUSINESS ASSURANCE  
NORWAY AS

Aud Løken Eiklid  
Certification Manager



Notified Body No.:  
0434

*This Certificate is valid until:*

**12 April 2020**

Angela Lanna  
Technical Reviewer

*This Certificate has been digitally signed. See [www.dnv.com/digitalsignatures](http://www.dnv.com/digitalsignatures) for more info*

**Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.**

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