

# CERTIFICATE

Number: 560228

The management system of:

## Duke Empirical, Inc

2829 Mission Street  
Santa Cruz, 95062  
USA

including the implementation meets the requirements of the standard:

# ISO 13485:2003

### Scope:

The design, development, and manufacture of guide catheters, dilatation catheters, vascular introducers, vascular drainage cannulas, dental implants, endoscopes, sutures, and extruded tubing for the areas of cardiovascular, dentistry, ENT, neurovascular, gastroenterology, obstetrics & gynecology, plastic surgery, radiology, urology and manufacture of in-vitro diagnostic medical devices used in genetic testing, prenatal screening, and tissue oxygen saturation including near patient/point of care.

Certificate expiry date: 1 March 2019  
Certificate effective date: 1 March 2018  
Certified since: 18 March 2003

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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