



# Certificate

No. Q5 083797 0007 Rev. 01

**Holder of Certificate:** **PT Esco Bintan Indonesia**  
Jalan Asoka Blok D6-D10  
Bintan Industrial Estate  
Lobam  
29154 Bintan  
INDONESIA

**Facility(ies):** PT Esco Bintan Indonesia  
Jalan Asoka Blok D6-D10, Bintan Industrial Estate, Lobam, 29154  
Bintan, INDONESIA  
  
See Scope of Certificate

**Certification Mark:**



**Scope of Certificate:** **Design, Development, Production,  
Final Assembly, Testing,  
Final Quality Assurance and Packaging of  
Incubators for Medical Applications**

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 083797 0007 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 083797 0007 Rev. 01)

**Report No.:** SIN\_5010185534\_RA\_2022

**Valid from:** 2022-08-05  
**Valid until:** 2025-08-04



**Date,** 2022-08-05

Christoph Dicks  
Head of Certification/Notified Body