CERTIFICATE

This is to certify that the company

Benchmark Electronics (Thailand) Public Company Limited

94 Moo 1, Hi-Tech Industrial Estate
Banlane, Bang Pa-In, Ayudhaya 13160
Thailand

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Manufacturing (including final inspection) of the following medical devices:
Powered laser surgical instrument with microbeam/fractional output; over-the counter Powered light based laser for acne; powered laser surgical instrument, electro-mechanical breast pump.
Ultrasonic Pulsed Doppler Imaging System, Endoscope processor, AED Acessory code Management and Arthroscope.
- AUS (a), BRA, JPN, CND, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	507052 MDSAP16
Certificate unique ID	170779649
Effective date	2022-03-25
Expiry date	2023-03-24
Frankfurt am Main	2022-03-11

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

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Product Manager

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DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.dqs.de/en/customer-database/ to validate this certificate.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 507052 MDSAP16
Certificate unique ID: 170779649
Effective date: 2022-03-25

Benchmark Electronics (Thailand) Public Company Limited

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Thailand

Audited site	REPs FEI No.: site scope and country-specific requirements
507052 **Benchmark Electronics (Thailand) Public Company Limited** 94 Moo 1, Hi-Tech Industrial Estate, Banlane, Bang Pa--In, Ayudhaya 13160 Thailand	Manufacturing (including final inspection) of the following medical devices: Powered laser surgical instrument with microbeam/fractional output; over-the counter Powered light based laser for acne; powered laser surgical instrument, electro-mechanical breast pump. Ultrasonic Pulsed Doppler Imaging System, Endoscope processor, AED Acessory code Management and Arthroscope. **- AUS (a), BRA, JPN, CND, USA (a,b,c,d)** **REPs FEI No.: F004969**

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Certificate registration No.: 507052 MDSAP16
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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821