



CERTIFICATE



This is to certify that the company

Gerium Medical Ltd.

6 Ha-Kishon St.
Yavne 8122017
Israel

with the organizational units/sites as listed in the annex

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

Scope of certificate and applicable country-specific requirements:
Design and development, manufacturing, distribution, installation and servicing of noninvasive bilirubin measuring devices for use in neonatal medical care
-BRA, CND

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 (MDSAP Audit Model Edition 2)

including country-specific requirements as shown in the scope
(full references are listed in the annex)

Certificate registration no.	517482 MDSAP16
Certificate unique ID	170703160
Effective date	2018-09-07
Expiry date	2021-09-06
Frankfurt am Main	2018-09-07



DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is authorised under the Medical Devices Single Audit Program.
Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



Annex to certificate
Certificate registration No.: 517482 MDSAP16
Certificate unique ID: 170703160
Effective date: 2018-09-07



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Audited site

Gerium Medical Ltd.

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Israel

DUNS No., site scope and country-specific requirements

Design and development, manufacturing, distribution,
installation and servicing of noninvasive bilirubin measuring
devices for use in neonatal medical care

-BRA, CND

DUNS No. 649181666



Annex to certificate

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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