CERTIFICATE

This is to certify that the company

HÄLSA Pharma GmbH

Maria-Goeppert-Str. 5
23562 Lübeck
Germany

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, development, manufacturing and distribution of physical acting products for the treatment of obstipation.
-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.	542575 MDSAP16
Certificate unique ID	170736461
Effective date	2019-08-05
Expiry date	2022-08-04
Frankfurt am Main	2019-08-05

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.mydqs.com/en/customers/customer-database.html to validate this certificate.

413.01.001 Version 2.0

Annex to certificate
Certificate registration No.: 542575 MDSAP16
Certificate unique ID: 170736461
Effective date: 2019-08-05

HÄLSA Pharma GmbH

Maria-Goeppert-Str. 5
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Audited site	DUNS No., site scope and country-specific requirements
HÄLSA Pharma GmbH Maria-Goeppert-Str. 5 23562 Lübeck Germany	Design, development, manufacturing and distribution of physical acting products for the treatment of obstipation. **-CND** **DUNS No.: 342599828**

Annex to certificate
Certificate registration No.: 542575 MDSAP16
Certificate unique ID: 170736461
Effective date: 2019-08-05

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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