# CERTIFICATE

This is to certify that the company

## Halkey-Roberts Corporation

2700 Halkey-Roberts Place North
Saint Petersburg, FL 33716
United States of America

with the organizational units/sites as listed in the annex

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

Scope of certification:
The design, development and manufacture of Swabable Straight Valves, Swabable Stopcock and Swabable Vial Adaptors for the medical industry.
**-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. | 539587 MDSAP16 |
| Certificate unique ID | 170777056 |
| Effective date | 2021-09-27 |
| Expiry date | 2024-09-26 |
| Frankfurt am Main | 2021-09-27 |

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

**DQS Medizinprodukte GmbH**

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

## Annex to certificate
## Certificate registration No.: 539587 MDSAP16
## Certificate unique ID: 170777056
## Effective date: 2021-09-27

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| Audited site | REPs FEI No.: site scope and country-specific requirements |
|---|---|
| **539587**<br>**HALKEY-ROBERTS CORPORATION**<br>2700 Halkey-Roberts Place North<br>Saint Petersburg, FL 33716<br>United States of America | The design, development and manufacture of Swabable Stopcock, Swabable Vial Adaptors and Contract Manufacture of the Swabable Straight Valves for the medical industry.<br>**-USA (a,b,c,d)**<br>**REPs FEI No.: F002087** |

# Annex to certificate
# Certificate registration No.: 539587 MDSAP16
# Certificate unique ID: 170777056
# Effective date: 2021-09-27

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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<br>(b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure |
| BRA | Brazil | RDC ANVISA n. 16/2013<br>RDC ANVISA n. 23/2012<br>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<br>Japan PMD Act (as applicable) |
| USA | United States | (a) 21 CFR Part 803<br>(b) 21 CFR Part 806<br>(c) 21 CFR Part 807<br>(d) 21 CFR Part 820<br>(e) 21 CFR Part 821 |