

Certificate

The Certification Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**Dale Medical Products, Inc.
40 Kenwood Circle, Suite 7
Franklin, MA 02038
United States of America**

has introduced, applies and maintains a Quality Management System in the area of:

**Manufacture and distribution of medical devices
as per attachment 1**

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:


EN ISO 13485:2016

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 09 February 2022

Report No.: 6452FS12F
Process No.: QS – 6452
Certificate No.: 6452GB445190830

Hamburg, 30 August 2019



MEDCERT Certification Body
(Lorenz Runge)

 **DAkkS**
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

**Attachment 1
Certificate
QS - 6452**

This attachment is valid only in connection with certificate No.: 6452GB445190830

**Manufacture and distribution of medical devices
in the field of patient care, acute care and rehabilitation**

- **Connectors for enteral nutrition**
- **Post-surgical bras**
- **Abdominal binders**
- **Bendable armboards**
- **Protectors and covers for IV cannulae**
- **Holders for:**
 - **tracheostomy tubes**
 - **endotracheal tubes**
 - **Foley catheters,**
 - **nasal dressings**
 - **transducer**

Sterile devices in the field of

- **General purpose securement device**
- **Intravascular catheter securement device**
- **Intravascular catheter securement device kit**

Hamburg, 30 August 2019



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