Certificate of Verification

Medical Device Safety Service GmbH (MDSS)

hereby declares that an Authorized Representative's Mandate according to the EU Regulation 2017/745 (MDR) is in place and that the following tasks have been carried out in accordance with the requirements of the MDR on behalf of the Manufacturer:

Dale Medical Products, Inc.

40 Kenwood Circle, Suite 7

Franklin, MA 02038-3298

USA

MDSS verified that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

MDSS keeps available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

MDSS complied with the registration obligations laid down in Article 123.3(d) and until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and/or 93/42/EEC have been applied.

Details of the device(s) covered by the Certificate are listed hereafter.

Issued: 2021-05-12

This Certificate is valid without signature. The document can be traced within MDSS' electronic system.

Certificate No.: 429821

This certificate is subject to the following terms and conditions:
It is only valid for the device(s) listed hereafter;
It is not a proof for compliance to CE marking;
The Manufacturer shall inform MDSS of any significant change(s) to the device(s) listed hereafter and MDSS will verify the change(s) and determine if a renewed certificate has to be issued;
As in accordance with the Directive 85/374/EEC Art. 1, the producer is liable for damages caused by a defect in his product(s). The Manufacturer in addition confirms that the requirements of Art. 10.16 of the MDR are fulfilled.
This Certificate of Verification is valid for 5 years or until expiry of the EU Declaration of Conformity or NB Certificate if applicable, whichever comes first.

Technical File	Generic Device Description/ Trade Name	GMDN or CND Code	Risk Class	EU Declaration of Conformity	NB Identification No. / NB Certificate No.	NB Cert. valid until YYYY-MM-DD	BfArM Registration Number*
ENDOTRACHEAL TUBE HOLDER April 2021	Dale Stabilock ET Tube Holder; Dale BREEZELOCK Endotracheal Tube Holder	35815	I	ENDOTRACHEAL TUBE HOLDER SERIES signed 23/04/2021	N.A.	N.A.	DE/CA09/0170/D03/014
FOLEY CATHETER TUBE HOLDER May 2021	Dale Hold-n-Place Foley Catheter Tube Holder Adhesive Patch; Dale Hold-n-Place Foley Catheter Tube Holder Leg Band	57982	I	FOLEY CATHETER HOLDER signed 05/05/2021	N.A.	N.A.	DE/CA09/0170/D03/015
ABDOMINAL BINDER April 2021	Dale Abdominal Binder	10003	I	ABDOMINAL BINDER SERIES signed 23/04/2021	N.A.	N.A.	DE/CA09/0170/D03/016
POST-SURGICAL BRA May 2021	Dale Post-Surgical Bra	10481	I	POST SURGICAL BRAS signed 05/05/2021	N.A.	N.A.	DE/CA09/0170/D03/017
NASAL DRESSING HOLDER April 2021	Dale Nasal Dressing Holder	58964	I	NASAL DRESSING HOLDER signed 23/04/2021	N.A.	N.A.	DE/CA09/0170/D03/018
TRANSDUCER HOLDER April 2021	Dale Transducer Holder	37318	I	TRANSDUCER HOLDER SERIES signed 23/04/2021	N.A.	N.A.	DE/CA09/0170/D03/019

*The registration number has been issued by the German Competent Authority.

Technical File	Generic Device Description/ Trade Name	GMDN or CND Code	Risk Class	EU Declaration of Conformity	NB Identification No. / NB Certificate No.	NB Cert. valid until YYYY-MM-DD	BfArM Registration Number*
ARMBOARD FAMILY April 2021	Dale Strapless Bendable Armboard; Dale Bendable Armboard	61139	I	ARMBOARD SERIES signed 23/04/2021	N.A.	N.A.	DE/CA09/0170/D03/020
I.V. ARMOR April 2021	Dale IV Armor Flexible Protective Overlay	61139	I	IV ARMOR signed 23/04/2021	N.A.	N.A.	DE/CA09/0170/D03/020
NASOGASTRIC TUBE HOLDER April 2021	Dale NasoGastric Tube Holder	36053	I	NASOGASTRIC TUBE HOLDER SERIES signed 23/04/2021	N.A.	N.A.	DE/CA09/0170/D03/021
TRACH. SERIES May 2021	Dale 240 Blue Tracheostomy Tube Holder; Dale 241 PediPrints Tracheostomy Tube Holder; Dale 242 PediPrints Tracheostomy Tube Holder; Dale 244 Blue Bariatric Tracheostomy Tube Holder	35752	I	TRACH SERIES signed 06/05/2021	N.A.	N.A.	DE/CA09/0170/D03/022

*The registration number has been issued by the German Competent Authority.