# EU DECLARATION OF CONFORMITY

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| Device Description | Laryngoscope handle, complete plastic (single use, non-sterile) |
| Basic UDI-DI | 42515859NLHDPN5 |
| UMDNS no. | 15-076 |
| GMDN code | 47806 |
| Classification | Class I, Rule 5, per annex VIII of the Regulation (EU) 2017/745 |

With the present declaration of conformity, we hereby declare, that the above-mentionedmedical device meets the applicable* safety and performance requirements, defined in annex I of the Regulation (EU) 2017/745 as amended by Regulation (EU) 2020/561.

The conformity assessment procedure has been performed self-dependent according to Art. 52, paragraph 7, and Art. *19of* the Regulation (EU) 2017/745, for class I medical devices. We confirm that we have established and maintain a technical documentation according to annex II and III of the Regulation (EU) 2017/745, to the extent* of and as per the applicable standards:

- Quality management system (ISO 13485:2016)
- General safety & performance (ISO 7376:2020)
- Risk management (ISO 14971:2019)
- Clinical evaluation (MEDDEV 2.7/1 Rev.4, MDCG 2020-5, MDCG 2020-6)
- Production processes & materials (ISO 7153-1:2016, ASTM F899-12b)
- Packaging, labelling & instructions of use (EN 1041:2008, ISO 15223-1:2016)
- Biocompatibility (Cytotoxicity ISO 10993-5:2009)
- Cleanliness (Bioburden ISO 11737-1:2018 guidelines)

According to Annex IV No. 2 of the Regulation (EU) 2017/745, we also declare that we, as the manufacturer, are solely responsible for issuing this EU Declaration of Conformity.

This declaration is valid until a revised declaration of conformity is issued.

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For Starkling e.K.
Emmingen-Liptingen, 21.03.2024