



To whom it may concern

Gilching, 15 February 2023

Statement

Instruction for use for the HEINE XP Disposable Laryngoscope Blades

According to annex I of the medical device regulation 2017/745 (EU), each device must be accompanied by information needed to use it safely and properly, taking account of the training and knowledge of the potential user. This information comprises the details on the label and the data in the instruction for use. As far as practicable and appropriated, the information needed to use the device safely must be set out on the device itself or on the packaging of each unit. The instruction for use must be included in the packaging for every device, unless the device is a class I device and can be used safely without any instruction for use.

The XP Disposable Laryngoscope Blades is a class I device. Because the device is only be used by qualified medical personnel, it is assumed that the device can be used safely without any instruction for use. Additional, all necessary information, which should be supplied by the manufacturer according to the medical device regulation 2017/745(EU), are contained on the packaging of each unit. An example for the Mac 4 blade is shown in the figure below:

HEINE QUALITY

XP Einmalgebrauchs-Laryngoskop Spatel
XP Disposable Laryngoscope Blade
Lame de laryngoscope à usage unique XP

The reuse and hygienic reprocessing of the XP Disposable Laryngoscope Blade leads to technical and functional limitations with regard to the requirements according to ISO 7376.

Mac 4

Verpackung erst unmittelbar vor Gebrauch öffnen
This package should only be opened immediately before use
Ouvrir l'emballage uniquement avant l'utilisation



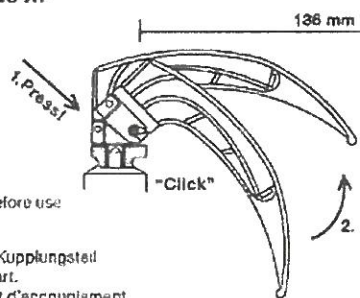
Siehe Prägung des Datumscodes auf dem Kupplungsteil
See date code imprinted on the coupling part.
Cf. marquage du code de date sur l'élément d'accouplement.



Anwendbar bis 5 Jahre nach Herstellungsdatum.
Can be used up to 5 years from the date of manufacture
Utilisable pendant 5 ans à partir de la date de fabrication.



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Furthermore, additional information is laid out in the instruction for uses MED0615 and MED112782. This instruction for uses contains the information for the safe use of the HEINE laryngoscope handles.


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