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Endoscopes — Bonnette d'oculaire et connecteur de fibres optiques

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Foreword

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: <u>Foreword - Supplementary information</u>

The committee responsible for this document is ISO/TG172, Optics and photonics, Subcommittee SC 5, Microscopes and endoscopes.

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Introduction

To carry out minimal invasive diagnostic or therapy requires not only endoscopes, but also some additional components like light guide cable, light source, and video-camera.

Sometimes these components are not from the same manufacturer. This Technical Specification is a recommendation to ensure the mechanical compatibility with these components.

If items are not from the same manufacturer, this kind of combination might not generate best results, but it allows the user to be able to work.

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Endoscopes — Eyepiece cap and light guide connector

IMPORTANT — Joint applications of different products are only permissible if the purpose and the relevant technical data are the same (working length, diameter, etc.). Injuries to the patient, user, or others, as well as damage to the products, are possible if the combination is not correct.

1 Scope

This Technical Specification specifies the design of eyepiece cap and light guide connector of an endoscope to enable the combination of products from different manufacturers. The products intended only for limited combination are out of the scope. It is a mechanical connection; it might not generate best results, but it allows the user to be able to work.

This Technical Specification supports manufacturers of components in the design of interfaces.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 2768-1, General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications

ISO 8600-6, Optics and photonics — Medical endoscopes and endotherapy devices — Part 6: Vocabulary

ISO 14971, Medical devices — Application of risk management to medical devices

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8600-6 and the following apply.

3.1

eyepiece cap

part located at the proximal end to which a photographic or video camera can be attached

3.2

light guide connector

part located at the proximal end which is designed to allow the connection of a *light guide cable* (3.3)

3 3

light guide cable

part which connects the endoscope to a light source for transmitting illumination

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4 Dimensions

4.1 Eyepiece cap

4.1.1 Eyepiece cap with straight edges

If the proximal image output is provided in the form of an eyepiece cap, it shall be designed in accordance to the details shown in Figure 1. These are the minimum requirements in terms of shape and design.

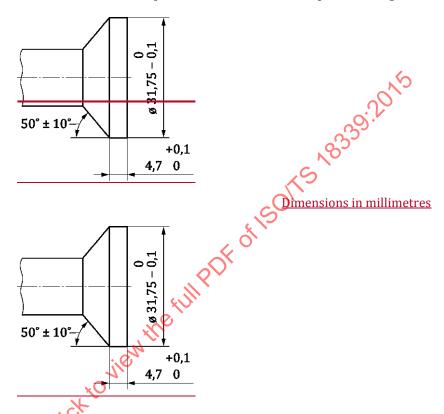


Figure 1 — Eyepiece cap with straight edges

4.1.2 Eyepiece cap with curved edges

Even if the eyepiece cap is designed with a radius, it will fit into the dimensions of this Technical Specification. See Figure 2.

Dimensions in millimetres