

## *Indian Standard*

# ANAESTHETIC AND RESPIRATORY EQUIPMENT — OROPHARYNGEAL AIRWAYS

## **1 Scope**

This International Standard specifies requirements for oropharyngeal airways of plastics materials and/or rubber, including those with a reinforcement insert made of plastics materials and/or metal.

This International Standard is not applicable to metal oropharyngeal airways, nor to requirements concerning flammability of oropharyngeal airways.

Flammability of oropharyngeal airways, for example if flammable anaesthetics, electrosurgical units or lasers are used, is a well-recognized hazard. It is addressed by appropriate clinical management, which is outside the scope of this International Standard.

This International Standard is not applicable to supralaryngeal airways without an internal, integral sealing mechanism.

## **2 Normative references**

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

ISO7000, Graphical symbols for use on equipment— Index and synopsis

ISO10993-1, Biological evaluation of medical devices— Part1: Evaluation and testing within a risk management process

ISO11607-1, Packaging for terminally sterilized medical devices— Part1: Requirements for materials, sterile barrier systems and packaging systems

EN556-1:2001, Sterilization of medical devices— Requirements for medical devices to be designated "STERILE"— Part1: Requirements for terminally sterilized medical devices

EN980, Graphical symbols for use in the labelling of medical devices

EN1041, Information supplied by the manufacturer with medical devices