NAMS/SANS 1866-2:2020

First Edition

SANS 1866-2:2018

NAMIBIAN STANDARD

Medical Devices
Part 2: Medical respirators

This Namibian standard is the identical implementation of SANS 1866-2:2018 and is adopted with the permission of the South African Bureau of Standards

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Foreword

This Namibian standard is the identical implementation of SANS 1866-2:2018 as approved by NSI TC 14 in accordance with the pursuance of the section 17 of the Government Gazette No. 7194, the NSI may during the State of Emergence, under section 20(1) of the Standards Act, 2005 (Act No. 18 of 2005) set, establish, and issue a Namibian standard, without having to follow the procedures for setting, establishing, issuing of a Namibian standard set out in the Standards Regulations published under Government Notice No. 249 of 20 September 2005.

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Medical devices

Part 2: Medical respirators

WARNING
This document references other documents normatively.

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SANS 1866-2:2018
Edition 1

Table of changes

Change No.	Date	Scope

Foreword

This South African standard was prepared by National Committee SABS/TC 1039, *Medical devices*, in accordance with procedures of the South African Bureau of Standards, in compliance with annex 3 of the WTO/TBT agreement.

This document was approved for publication in March 2018.

Reference is made in A.1.2 to the "relevant national legislation". In South Africa this means the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).

SANS 1866 consists of the following parts, under the general title *Medical devices:*

Part 1: Medical face masks.

Part 2: Medical respirators.

Annex A forms an integral part of this document.

Compliance with this document cannot confer immunity from legal obligations.

Introduction

An air purifying medical respirator provides a barrier to prevent healthcare workers from inhaling infective airborne agents such as bacteria and viruses. The level of protection a medical respirator provides is determined by the efficiency of the filter material and the extent to which the face piece fits or seals to the healthcare worker's face. A number of studies have shown that surgical masks alone do not provide adequate protection in filtering out infective airborne agents. Surgical masks are not respirators; they do not comply with the necessary requirements for respiratory protection.

Respirators are designed to have the characteristics of both an approved respirator and a surgical mask. In the United States these products, typically referred to as "Surgical respirators", are approved by the National Institute for Occupational Safety and Health (NIOSH) and are cleared by the US Food and Drug Administration (FDA) for use in surgery. In Europe medical respirators, referred to as "Health care respirators", are tested in accordance with EN 149 and are endorsed by both the European Medical Devices Directive and the Personal Protective Equipment (PPE) Directive.

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