

## Control and safety valves

# Technical document 079-11

Additional specifications for products intended for the medical sector

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## MODIFICATION HISTORY

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## TABLE OF CONTENTS

### I. TESTS ON THE RESISTANCE OF MATERIALS USED IN MEDICAL ENVIRONMENTS TO DISINFECTANTS----- 5

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1.	Foreword .....	5
2.	Field of application .....	5
3.	Principle of the test .....	5
4.	Procedure .....	5
4.1.	Curative treatment .....	5
4.2.	Preventive treatment .....	6
4.3.	Test sequence .....	6
4.4.	Requirements .....	6
5.	Marking - Location .....	6

# I. TESTS ON THE RESISTANCE OF MATERIALS USED IN MEDICAL ENVIRONMENTS TO DISINFECTANTS

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## 1. Foreword

The specific "M" marking has been created to meet the expectations of market players who require performance levels that exceed or complement product standards for valves used in the medical sector.

An ageing test has been defined for these valves to meet the need for disinfection.

This is a voluntary approach and complements the assessment of a product that is already certified as compliant with the standards

## 2. Field of application

This document applies to taps installed inside buildings open to the public (the delivery point is not affected), EPHAD and hospitals, referred to in the rest of the document as "medical environment".

It defines the disinfection test protocols for devices that may be used in medical environments.

The corresponding test and assessment methods and the associated marking are defined.

## 3. Principle of the test

The test consists of subjecting devices installed in drinking water systems to :

- cycles of contact with disinfection products to check their compatibility with these products,
- thermal shock cycles for disinfection.

The frequency of these tests is set at every 5 years.

## 4. Procedure

When new, the devices are mounted on a circulation loop and subjected to disinfection treatments of the following types:

- o curative
- o preventive

The samples must be tested beforehand in accordance with the characterisation tests described in the standards and technical documents for each family of devices.

### 4.1. Curative treatment

Apply one of the treatments listed in the table to each sample.

Each sample is subjected to only one treatment.

The 20 repetitions will be carried out continuously without a treatment stop period

**Table 1 – Curative treatment**

Treatment	Circulation time	Concentration	Water temperature	Number of cycles	Sample	Functional assessment
NaClO Sodium hypochlorite	1 h	100 mg/l	< 30°C	20	n°1, n°1bis	No object
H2O2 Hydrogen peroxide	2 h	1 g/l	< 30°C	20	n°2, n°2bis	No object
Thermal shock	0,5 h	/	70°C +/-2 °C	20	n°3, n°3bis	No object

## 4.2. Preventive treatment

Apply one of the treatments shown in Table 2 to each sample.

A sample undergoes only one treatment.

**Table 2 – Preventive treatment**

Treatment	Circulation time	Concentration	Water temperature	Number of cycles	Sample	Functional assessment
NaClO Sodium hypochlorite	3 months	1 mg/l	50°C+/-2°C	uninterrupted	n°1, n°2, n°3	product norm
ClO2 Chlorine dioxide	3 months	1 mg/l	50°C+/-2°C	uninterrupted	n°1bis, n°2bis, n°3bis	product norm

## 4.3. Test sequence

Six samples are required to carry out the tests.

Two samples will come into contact with a solution used for curative treatment (table 1).

At the end of the curative treatment, the samples are examined visually.

After this initial phase, the samples are contacted with a solution defined as part of the preventive treatment (table 2).

At the end of these contacts and without waiting, the sample will be rinsed with drinking water from the network.

After rinsing, the characterisation tests defined in the product standard will be carried out on the samples.

## 4.4. Requirements

During the "treatment" phases, there must be no visible degradation.

The characterisation tests are defined in the standards and technical documents for each family and are identical to those carried out after endurance.

## 5. Marking - Location

Where appropriate, devices may be permanently and legibly marked with the letter "M" to distinguish them.

Commercial documentation must specify that the device may be intended for medical use.