

### **Declaration on Product Standards**

We, RUDOLF Medical GmbH + Co. KG, hereby confirm the compliance with the following standards:

#### **DIN EN ISO 13402**

# Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure

All RUDOLF Medical products which are made of stainless medical grade steel, and which are treated gently are corrosion resistant according to DIN EN ISO 13402 (Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure).

### DIN 58298 Medical instruments - Materials, finish and testing

Please note that the DIN 58298 standard has been replaced by the following standards:

- DIN 96298-1 Medical instruments Terms, measuring methods and tests Part 1: Terms and definitions
- DIN 96298-2 Medical instruments Terms, measuring methods and tests Part 2: Measuring methods for the determination of basic measurements of surgical standard instruments
- DIN 96298-3 Medical instruments Terms, measuring methods and tests Part 3: Tests

## ISO 7741 Instruments for surgery; Scissors and shears; General requirements and test methods

This standard deals with materials, heat treatment and hardness of component parts, corrosion resistance, workmanship and cutting ability of scissors and shears used in the surgery and defines the test methods.

#### ISO 7153-1 Surgical instruments - Materials - Part 1: Metals

This standard specifies metals commonly used to manufacture various types of standard surgical instruments, including but not limited to those used in general surgery, orthopaedics, and dentistry.

Sincerely, RUDOLF Medical GmbH + Co. KG

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