

# Zumias International

## DECLARATION OF CONFORMITY CLASS 1 SURGICAL INSTRUMENTS

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The medical devices manufactured by Zumias International are designed to perform specific functions such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating, suturing, or ligating and other similar procedures. They may also be used to facilitate the insertion of surgical implants.

We, Zumias International, declare that the Class 1 Surgical Instruments listed and coded within the company catalogue meet the essential requirements of Directive No. 93/42/EEC and Updated Directive 2007/47/EEC and are manufactured in accordance with our Quality Management System certified to ISO9001:2015, ISO13485:2016. This declaration is valid for all instruments (see Attachment 1) sold under the following brandnames: Beautytools, Beautytools.be, Beauty Tools, Zumias, Zumias International, Deforce Medical and Nilsson. Zumias International holds the sole rights to add brandnames to this list in the future. Where applicable, our products are manufactured in accordance with and from materials suitable for sterilization in accordance with the requirements of one or more of the recognized standards and guidance documents listed below:

Standard	Details
BS EN ISO 9001:2008	Quality Management Systems certification standard.
BS EN ISO 13485:2003	Medical Devices – Quality Management Systems certification standard.
MDD 93/42/EEC, Annex II, Section 3.2	Medical Device Directive, 'EC Declaration of Conformity' (full quality assurance system).
MDD 93/42/EEC, Annex I	Essential Requirements for Medical Devices.
S EN ISO 7153- 1:2001 (BS 5194:Part 1:1991)	Surgical Instruments – Metallic materials part 1 - Stainless Steel
BS 5194:Part 2:1989	Specification for instruments with pivot joints (excluding cutting instruments)
BS 5194:Part 3:1985	Specification for Dissecting Forceps
BS 5194:Part 4:1985	Specification for scissors, shears, and other jointed cutting instruments
ISO 7151:1988	Surgical instruments – non-cutting, articulated instruments – general requirements & test methods
ISO 7740:2004	Scalpels with detachable blades - Fitting dimensions
ISO 7741:1986	Scissors and shears - General requirements and test methods
ISO 6508-1:2005 (DIN 50103- 3:1995)	Specifies the method for Rockwell and Rockwell superficial hardness tests for metallic materials.
BS EN ISO 14971:2012	Medical Devices – Application of risk management to medical devices.
DIN 58298:2010-09	Medical instruments - Materials, finish and testing.
DIN 58299:1964-01	Serrations for surgical instruments; profile angles, groove distances.
DIN 58300:1982-02	Joints for surgical instruments.
HTM 2010	Recommendations for sterilization
AS/NZ 4187-2003	Cleaning, disinfecting & sterilising of re-usable surgical instruments


For and on behalf of Zumias International

  
ZUMIAS INTERNATIONAL  
PARTNER

Zubair Maher – CEO – 14<sup>th</sup> June 2023

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### ATTACHMENT 1

This declaration is valid for all article/EAN-numbers listed below. Zumias International holds the sole rights to add article/EAN-numbers to this list in the future.

#### Article/EAN-numbers:

5407007719006	7434017844822	5407007710515
5407007719013	7434017851882	5407007712700
5407007719020	7434017851899	5407007710522
5407007719037	7434017852803	5407007711161
5407007719044	7435119862844	5407007710546
5407007719051	7435119864824	5407007710546
5407007719068	7435119864831	5407007712441
5407007719075	7435119864855	5407007710539
5407007719082	5407007710898	5407007712434
5407007719099	5407007710904	5407007710508
5407007719105	5407007710911	5407007712458
5407007719112	5407007710928	5407007711154
5407007719129	5407007710935	5407007710553
5407007719136	5407007711178	
5407007719143	5407007711185	
5407007719150	5407007711192	
5407007719167	5407007712298	
5407007719174	5407007712410	
5407007719181	5407007712427	
5407007719198	5407007712984	
5407007719204	5407007712991	
5407007719211	5407007713004	
5407007719228	7434017847861	
5407007719235	7434017847878	
5407007719242	7434017847885	
5407007719259	7435119862882	
5407007710560	7434017847892	
5407007710584	7435119863810	
5407007710591	7435119864817	
5407007710607	7434017848806	
5407007711796	5407007710492	
7434017844815	5407007711147	

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