

DECLARATION OF CONFORMITY


Manufacturer:	<p align="center">ZHERMACK SPA VIA BOVAZECCHINO, 100 45021 BADIA POLESINE (RO) ITALY</p>		
Product:	CODE	NAME	DESCRIPTION
	C306550	ZETACLAVE B	18 Litres
	C306552	ZETACLAVE B	23 Litres
Accessories:	<p>Manual thermostealing machine, Electric distiller, Demineralizer, Refill cartridges for demineralization, Osmosis, Refill cartridges kit Osmosis, STS data logger, Reversible tray holder for 18lt, Reversible tray holder for 23lt, Roll of printer paper, Helix test, Bowie and Dick Test, Chemical indicator, Spores, bacterial filter, door seal, stainless steel filter, resistor for sealing machine 1000w, softener powder for distiller, cutter for sealing machine, After sale kit, Activated carbon, Tray for Zetaclave 18lt, Tray for Zetaclave 23lt., Kit Zetaclave</p>		
Intended use:	Medical device designed for steam sterilization of small sided tools and equipments.		
Classification:	CLASS IIb, RULE 15 ANNEX IX OF THE MDD 93/42/CEE AMENDED BY 2007/47/CE		
<p>WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/CEE AMENDED BY 2007/47/CE FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.</p>			
<u>Standards applied :</u>	UNI EN ISO 13485 :2012 <u>UNI CEI EN ISO 14971:2012</u> UNI CEI EN ISO/IEC 17050-1 : 2010		
<u>Technical Standards ref.:</u>	CEI EN 61326-1 Electrical equipment for measurement, control and laboratory use, 2004/108/CE Electromagnetic compatibility, 2006/95/CE Electrical material used within certain limits of tension, 73/23/CEE I Low voltage 89/336/CEE Electromagnetic Compatibility CEI EN 61010-1 Safety prescriptions for electrical, measuring, control and laboratory equipment CEI EN 61010-2-40 Safety prescriptions for sterilizers and disinfectors used for treating medical materials 97/23/CE Pressure vessels EN13060 Small steam sterilizers		
EC Certificate:	According to Annex II section 3 of the Directive 93/42/EEC N. G1 12 08 53618 016 valid until 2017/08/27 TUV SUD PS (0123)		

REVISIONE	DATA	DESCRIZIONE
0	30/07/07	Prima emissione
1	11/06/08	Aggiornamento formato e inserimento zetaclave S
2	12/05/09	Modifica ruolo Presidente e Nome
3	03/09/09	Aggiunta accessori
4	25/03/10	Aggiornamento secondo dir. 2007/47/CE
5	24/08/10	Inserimento dati ente certificatore RAP 02/10
6	14/01/2011	Inserimento nuovi codici e accessori
7	26/07/2011	Aggiornamento norme tecniche
8	23/04/2012	Aggiornamento firma, aggiunta campo validità dichiaraz., aggiornamento norme
9	04/09/12	Nuovo certificato CE
10	02/01/2013	Eliminazione sportelli colorati
11	03/02/2014	Eliminazione Zetaclave S e aggiornamento norme

	Ridlerstrasse 65, 80339 Munchen - Germany
Validity of Declaration of conformity:	Valid until: 27/08/2017
Start of CE marking:	C306550 serial number 20070715 dated 27/07/07 C306552 serial number 20070004 dated 12/09/07

Badia Polesine, 03/02/14

Paolo Ambrosini



General Manager
Zhermack SpA

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