

Manufacturer **W&H Sterilization S.r.l.**

Address Via Bolgara, 2  
I-24060 Brusaporto (BG)  
ITALY

Series 

Type/model **PRO13-003-17; PRO13-003-22**

REF See attached table

Serial Number **XXXXXX**

Technical Specifications

Classification (MDD, Annex IX)/Rules : IIb / 15

We herewith declare under our sole responsibility that the above mentioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of manufacturer and the notified body.

Technical file: TF 17

The sterilizer, sterilization processes and provided documentation are in full compliance with the following applicable DIRECTIVES and STANDARDS.

Directive

Medical Device Directive: COUNCIL DIRECTIVE of 14 June 1993 concerning medical devices (MDD 93/42/EEC amended by Directive 2007/47/EC – DL 24-02-1997, n°46 modified by DL 25-01-2010 n° 37), Annex I

Standards

INTERNATIONAL		EUROPEAN		ITALIAN	
		EN 13060 + A2	2010	UNI EN 13060	2010
IEC 61010-1	2001	EN 61010-1	2001	CEI EN 61010-1	2001
IEC 61010-2-040	2005	EN 61010-2-040	2005	CEI EN 61010-2-040	2005
IEC 61326-1	2012	EN 61326-1	2013	CEI EN 61326-1	2013

Notified Body:

**IMQ** S.p.A.


Via Quintiliano, 43 – 20138 Milano, Italy

Conformity Assessment Route:

Annex II

Date CE mark was affixed:

Certificate n° 780/MDD of 2016/01/08

ISSUE DATE	APPROVED BY
08 January 2016	 Simone Previcini General Management

W&H Sterilization S.r.l. - Via Bolgara, 2 - 24060 Brusaporto (BG) Italy

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DESCRIPTION	TYPE/MODEL	REF
Small Steam Sterilizer	PRO13-003-17	19941103
	PRO13-003-17	19941104
	PRO13-003-17	19941105
	PRO13-003-22	19942103
	PRO13-003-22	19942104
	PRO13-003-22	19942105