

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

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

Series 

Type/model **PRO13-001-17; PRO13-001-22; VA131-17; VA131-22**

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 16

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	2014	UNI EN 13060	2015
IEC 61010-1	2010	EN 61010-1	2010	CEI EN 61010-1	2010
IEC 61010-2-040	2015	EN 61010-2-040	2015	CEI EN 61010-2-040	2016
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 2019/06/13

ISSUE DATE	APPROVED BY
13 June 2019	 Simone Previcini General Management
W&H Sterilization S.r.l. - Via Bolgara, 2 - 24060 Brusaporto (BG) Italy	

DESCRIPTION	TYPE/MODEL	REF
Small Steam Sterilizer	PRO13-001-17	19931110
	PRO13-001-22	19932110
	VA131-17	19931110
	VA131-17	19931111
	VA131-17	19931112
	VA131-17	19931113
	VA131-17	19931114
	VA131-17	19331115
	VA131-17	19931120
	VA131-17	19931121
	VA131-17	19931122
	VA131-17	19931130
	VA131-17	19931131
	VA131-17	19931180
	VA131-17	19931181
	VA131-17	19931182
	VA131-17	19931183
	VA131-17	19931184
	VA131-17	19931185
	VA131-22	19932110
	VA131-22	19932111
	VA131-22	19932112
	VA131-22	19932113
	VA131-22	19932114
	VA131-22	19932115
	VA131-22	19932121
	VA131-22	19932122
	VA131-22	19932130
	VA131-22	19932180
	VA131-22	19932181
	VA131-22	19932182
	VA131-22	19932183
VA131-22	19932184	
VA131-22	19932185	