



DECLARATION OF CONFORMITY O2 SENSORS CLASS II a

3.4		C 111		
Manufacturer:		Carril Instruments, s.l.		
		Congost, 28		
		ES-08024 Barcelona, Spair	ı	
We herewith declare that the following products meet the provisions of the Council Directive 93/42/EEC for Medical				
Devices Annex II.3. All supporting documentation is retained under the premises of the Manufacturer.				
Family	Model #		Classification	Rule
O2 Sensors	E-01, E-02, E-03, E-04, E-05, E-06, E-07, E-07ST,		IIa	2
	E-08, E-09, E-10, E-11, E-12, E-13, E-14, E-14ST, E-			
	15, E-15TD, E-16, E-16HT, E-18, E-25, E-43, E-48, E-			
	60HC, E-80.			
Standards Applied 02 Sensors:		EN 14971		
**		EN 60601-1		
		EN 60601-1-2		
		Directive 2011/65/EU Anne	ex IV exemption	
Notified Body:		EMKI		
•		3, Diós arók		
		H-1125 Budapest		
		Hungary		
		Identification # 1011		
EC Certificate:		5-726-200-1211		
Start of CE Marking:		July 27 th 2004		
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Place, Date of Issue:		Barcelona, Spain, October 7	7 th 2015	

Signature:

Fernando Noguero

Manager, Regulatory Affairs & Quality Assurance

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