



I.P.S. MEDICAL SRL

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**DECLARATION OF CONFORMITY
VETERINARY MEDICAL DEVICE
In accordance with UNI EN 17050-2005**

MANUFACTURER	I.P.S. MEDICAL S.r.l. Via dell'Agricoltura, 22/24 – 37012 Bussolengo (Vr) Italy
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HEREBY DECLARE THAT:

EQUIPMENT	X-RAY UNIT
MODEL	PHILOSOPHY HF400
ELECTRONIC SYSTEM	
GENERATOR	
TUBE TYPE KL65	
COLLIMATOR	
MANUFACTURED	

is in conformity with the applicable requirements of the following documents

- Dir. 2014/30/UE** Council Directive concerning electromagnetic compatibility
- IEC 60601-1:2005** Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - requirements and tests
- IEC 60601-1-3:2008** Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-28:2010** Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC 60601-2-54:2009** Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all applicable Essential Requirements of the Directives.

Bussolengo, //

Antonella Travaglia
General Manager