

DICHIARAZIONE DI CONFORMITA' UE EU DECLARATION OF CONFORMITY

ITALRAY s.r.l.

Via Del Parlamento Europeo 9D - 50018 SCANDICCI (FIRENZE) ITALY
SRN: IT-MF-000014620

sotto la propria ed unica responsabilità dichiara che il dispositivo medico:
under our own and sole responsibility declares that the medical device:

Prodotto/Product	XFM
Basic UDI-DI	805411068-XFM-W9
REF	AMR+IR303-A
	AMR+IR303-B
	AMR+IR313-A
	AMR+IR313-B
	AMR+IR323-A
	AMR+IR323-B
Classe/Class	II b (Annex VIII rule 10 MDR 2017/745)

è conforme ai requisiti generali di sicurezza e prestazione, Allegato I del Regolamento UE 2017/745 ed ai requisiti essenziali della Direttiva Macchine 2006/42/CE. *Complies with the general safety and performance requirements, Annex I of the EU Regulation 2017/745 and the essential requirements of the Machinery Directive 2006/42/EC.*

Il dispositivo è conforme alle presenti norme / *The device complies with these standards:*

EN 60601-1	Medical electrical equipment. General requirements for safety
EN 60601-1-2	Medical electrical equipment. General requirements for safety - Collateral standard: Electromagnetic compatibility – requirements and test.
EN 60601-1-6	Medical electrical equipment. - Part 1: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366	Medical devices - Application of usability engineering to medical devices.
EN 60601-2-54	Medical electrical equipment - Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
EN 60601-1-3	General requirement for radiation protection in diagnostic X-Ray
EN 60601-2-28	Medical electrical equipment. - Part 2: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.

La marcatura CE del prodotto è stata eseguita dall'organismo notificato IMQ n° 0051 secondo la procedura di valutazione di conformità Allegato IX CAPO I (Certificato n° 058/MDR)
The CE marking of the product was performed by the notified body IMQ n° 0051 according to the conformity assessment procedure Annex IX CHAPTER I (Certificate n° 058/MDR)



Scandicci

24/10/2022

ITALRAY srl
Lamberto Marzocchi
general manager

