DICHIARAZIONE DI CONFORMITA' CE
STATEMENT OF COMPLIANCE EC
DECLARATION DE CONFORMITE CE

N° 4608

secondo il punto 2 dell'allegato II della direttiva 93/42/CEE e successive modifiche
according to point 2 of the annex II of the 93/42/CEE directive and subsequent amendments
selon le point 2 de l'annexe II de la directive 93/42/CEE et ses modifications ultérieures

ITALRAY s.r.l.

sotto la propria ed unica responsabilità dichiara che il dispositivo medico:
under our own and sole responsibility declares that the medical device:
sous propre et seule responsabilité déclare que le dispositif médical:

Model	X-FRAME DRF	
REF - SN	SRD+IR700/A-B	21-269-22
Classification	EN 60601-1 **I type B**	annex IX 93/42/CE **II b**

è conforme ai requisiti essenziali della direttiva 93/42/CEE e successive modifiche
is compliance with the applicable requirements of 93/42/EEC directive and subsequent amendments
est conforme aux conditions applicables de la directive 93/42/CEE et ses modifications ultérieures

di seguito una sintesi delle norme a cui risulta conforme:
hereinafter a summary of the rules is found to be compliant:
ci-après, un résumé des règles est jugé conforme:

EN 60601-1	:2006/A1:2013 Medical electrical equipment. General requirements for safety
EN 60601-1-2	:2015 Collateral standard: Electromagnetic compatibility, requirements and test
EN 60601-1-6	:2010/A1:2015 Medical E.E. General requirements for basic safety and essential performance - Usability
EN 62366-1	:2015 Medical devices - Application of usability engineering to medical devices.
EN 60601-2-54	:2009 Medical E.E. Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
2011/65/EU	Devices are compliance with the European Directive 2011/65/EU RoHS

La marcatura CE del prodotto è stata eseguita dall'organismo notificato IMQ n° 0051
The CE marking of the product was performed by the notified body IMQ n° 0051
Le marquage CE du produit a été effectuée par l'organisme notifié IMQ n° 0051

CE 0051

Scandicci

01/03/2022
REF 2059/MDD

ITALRAY srl
Lamberto Marzocchi
general manager