

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

N° 2365

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 DR2S SYSTEM	
REF - SN	SRD+IR604/A-A	02-147-15
Classification	EN 60601-1 I type B	annex IX 93/42/CE II b
Composed by	X-Frame DR; Pixel CP; BS45; Statix Synchro; BTE, accessory	

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

In particolare risulta conforme alle seguenti norme:
In particular it complies with the following standards:
En particulier il est conforme aux normes suivantes:

EN 60601-1	:2006-10 Medical electrical equipment. General requirements for safety
EN 60601-1-2	:2007/AC2010 Collateral standard: Electromagnetic compatibility, requirements and test
EN 60601-1-6	:2010 Medical electrical equipment. - General requirements for basic safety and essential performance - Collateral standard: Usability
2011/65/EU	Devices are compliance with the European Directive 2011/65/EU RoHS

La marcatura CE del sistema è stata eseguita dall'organismo notificato DNV GL Business Assurance AS n°0434
Le marquage CE du système a été effectuée par l'organisme notifié DNV GL Business Assurance AS n°0434
The CE marking of the system was performed by the notified body DNV GL Business Assurance AS n°0434

Scandicci



25/07/2022

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ITALRAY srl
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