



DECLARATION OF CONFORMITY

Following the provisions of the medical device directive 93/42/EEC, Annex II

We

Manufacturer:

**GE Medical Systems, LLC
4855 West Electric Avenue
Milwaukee, WI 53219 USA**

EU Authorized Representative:

**GE Medical Systems SCS
283 rue de la Minière
78530 BUC, France**

Manufacturing sites:

Site #1

**GE Medical Systems, LLC
4855 West Electric Avenue
Milwaukee, WI 53219 USA**

Site #2

**GE BE PRIVATE LIMITED
#60 Export Promotion Industrial Park
Whitefield, Bangalore 560066 INDIA**

Site #3

**GE Medical Systems SCS
283 rue de la Minière
78530 BUC, France**

Site #4

**GE MEDICAL SYSTEMS MONTERREY MEXICO SA DE CV
Parque Industrial Huinala Calle Espana 300
66645 Apodaca NL MEXICO**

Declare under our sole responsibility that the device:

**X-Ray Tube Housing Assemblies (Housing and Tube)**

Ref (Catalog Designation / Part Number): Reference Addendum to the Declaration of Conformity

GMDN Code: **35618**Classification rule (93/42/EEC Annex IX): **10** Class: **IIb**

To which this declaration relates, is in conformity with the requirements of the medical device directive 93/42/EEC which apply to it.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
 - Technical Documentation/DHF Ref./ réf, of the product to which this declaration relates:
DOC0819831, DOC0380539, DOC0848726, DOC0862891, DOC0842659, DOC0856374, DOC1196928
 - EC certificate: approval of full quality assurance system (Annex II of the directive 93/42 EEC) delivered by GMED SAS (Notified Body 0459) / Certificate N° 22462
 - Harmonized standards applied on the product to which this declaration relates:

Standards Applied	X-Ray Tube Housing Assembly (ref. Addendum to the Declaration of Conformity)
EN 60601-2-28:2010	MX100 HTG, MX100 FL, Maxiray MX100 FL, MX75 HRT, Maxiray HRT 275, MX150, MX165CT HiSpeed Advantage, Maxiray CT HSA, MX135CT Sri, Maxiray CT Sri, Performix Advantage CTI, Maxiray CT Advantage CTI, MX200CT NP/Performix, Performix Advantage/Lightspeed, Maxiray CT Advantage, MX200CT/Performix Ultra, Maxiray CT Ultra, Performix 40, MX135CT HiLight Advantage, Maxiray CT HLA, MX115 WJ, Maxiray CT Pace,
IEC 60601-2-28:2017	MX100 RAD, Maxiray MX100 RAD, Performix 160A, MX165CT ProSpeed, Maxiray MX165CT ProSpeed, MX165NP/ Solarix 350 Brightspeed, Maxiray Solarix, Performix Pro VCT 100, Maxiray CT VCT, Performix HD, Performix 40 Plus, Performix Plus

Waukesha, WI USA


Amy Yang
Regulatory Affairs Manager

This EC declaration of conformity supersedes the previous declaration of conformity dated 9-July-2018

**ADDENDUM TO THE DECLARATION OF CONFORMITY**

Product Description	Catalog Designation
MX100 HTG	D2251C, D2252C
MX100 FL *Maxiray MX100 FL	D2262F, D2281F, D2282F, *D2289F, D2311F, D2312F, *D2319F
MX100 RAD *Maxiray MX100 RAD	D2282R, D2342R, D2301R, D2302R, *D2309R, D2311R, D2312R, *D2319R, 5237529, 5237530
MX75 HRT *Maxiray HRT 275	D2631P, D2632P, *D2639P, D2641P, D2642P, *D2649P
MX150	D2711C, D2712C
Performix 160A	D2801A, D2804A, D2805A
MX165CT HiSpeed Advantage *Maxiray CT HSA	D3101T, D3102T, *D3109T
MX165CT ProSpeed *Maxiray MX165CT ProSpeed	D3111T, D3112T, *D3119T
MX135CT Sri *Maxiray CT Sri	D3121T, D3122T, *D3129T
Performix Advantage CTI *Maxiray CT Advantage CTI	D3131T, D3132T, *D3139T
MX165NP/ Solarix 350 Brightspeed *Maxiray Solarix	D3141T, D3142T, D3145T, D3146T, *D3149T, 5373079, 5373080
MX200CT NP/Performix	D3151T, D3152T
Performix Advantage/Lightspeed *Maxiray CT Advantage	D3175T, D3176T, *D3179T
MX200CT/Performix Ultra *Maxiray CT Ultra	D3185T, D3186T, *D3189T, D3885T, D3886T
Performix 40	D3187T, D3188T
Performix Pro VCT 100 *Maxiray CT VCT	D3193T, D3194T, D3195T, D3196T, D3194TR, *D3199T
MX135CT HiLight Advantage	D3201T, D3202T, D3209T
MX115 WJ *Maxiray CT Pace	D3301T, D3302T, D3307T, *D3309T
Performix HD	D3701T, D3702T, D3703T, D3704T
Performix 40 Plus	D3887T, D3888T
Performix Plus	D3889T, D3890T