GE Yokogawa Medical Systems

DECLARATION CE DE CONFORMITE

(SUIVANT LES DISPOSITIONS DE LA DIRECTIVE RELATIVE AUX DISPOSITIFS MEDICAUX 93/42/CEE)

EC DECLARATION OF CONFORMITY

(FOLLOWING THE PROVISIONS OF THE MEDICAL DEVICES DIRECTIVE 93/42/EEC)

Nous / *We* ,

Fabricant / *Manugacturer*

GE Yokogawa Medical Systems, Ltd.
4-7-127, Asahigaoka,
Hino-shi, Tokyo,
191-8503 Japan

Responsable U.E. / *E.U. Responsible*

GE Medical Systems S.C.S.
283 Rue de la Miniére
78533 BUC CEDEX
FRANCE

déclarons, sous notre seule responsabilité, que le produit de classe II b :
declare under our sole responsibility that the class II b product :

BrightSpeed Elite

X-ray system, diagnostic, computed tomography, full-body

Réf./ *ref.* : Voir addendum joint. / See Addendum

GMDN code : **37618**

Lieu de fabrication / Manufactured in :

GE Yokogawa Medical Systems, Ltd – Tokyo, Japan
GE Hangwei Medical Systems Co.Ltd – Beijing, China PRC

auquel cette déclaration se rapporte, est en conformité avec les exigences essentielles qui lui sont applicables (annexe I de la directive relative aux dispositifs médicaux 93/42/CEE).
to which this declaration relates is in conformity with the essential requirements which apply to it (annex I of the medical devices directive 93/42/EEC).

Cette conformité s'appuie sur les éléments suivants / *This conformity is based on the following elements:*

- Informations contenues dans le(s) document(s) / *Information included in the document(s):*
  Dossier historique de conception / *Design History File*
  Réf./ *ref.* : **Technical File for BrightSpeed series MTR-SRECT-B120 rév/rev. 8 date : 18, December, 2008**
  (Developed name is HiValue)
  du produit auquel cette déclaration se rapporte / *of the product to which this declaration relates.*
- Attestation CE d'approbation du système complet d'assurance qualité (annexe II de la directive relative aux dispositifs médicaux 93/42/CEE) délivrée par le G-MED (Organisme Notifié n° 0459) / *EC certificate : approval of full quality assurance system (annex II of the medical devices directive 93/42 EEC) delivered by G-MED (Notified Body n° 0459).*
  Attestation / *Certificate* N° 7834.

Date: December 25 2008

Tokyo Japan, le 25 decembre 2008
Tokyo Japan, December 25, 2008

Daisuke Tanaka

Daisuke TANAKA
Manager, Q & E System Group
Quality Assurance Division
GE Yokogawa Medical Systems

Cette déclaration CE de conformité remplace la précédente déclaration datée du 19 mars , 2008.
This EC declaration of conformity replaces the previous declaration dated 19 March, 2008.

ADDENDUM (1/1) A LA DECLARATION CE de CONFORMITE datée du 25 DECEMBRE 2008

Addendum (1/1) to the EC Declaration of Conformity dated December 25, 2008

BrightSpeed Elite

DESCRIPTION DU PRODUCT *Product Description*	REFERENCE CATALOGUE *Catalog Designation*
BrightSpeed Elite Made by Japan	**B75032BS** **B75042BS**
Consisting of ;	
CT Gantry	B70062BS B70092BS
Patient Table	B78052AD
Operator Console	B75002BS
Power Distribution Unit	B75352AD
Ship Collector	B75052BS
Technical Publication	B75012BS
LCD Monitor	B78582LC
Made by China	**B77142CA**
Consisting of ;	
CT Gantry	B79182CA
Patient Table	B79172CA
Operator Console	B77172CA
Power Distribution Unit	B70942CA
Ship Collector	B77242CA
Technical Publication	B77212CA
LCD Monitor	B71292CA