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VIA SAGITTARIO, 5  
40044 PONTECCHIO MARCONI  
BOLOGNA - ITALY  
TEL. 051/84.68.51 (R.A.)  
FAX 051/84.68.56  
E-mail: imscmm@tin.it - imstech@tin.it

Docket No. 00D-1497  
Dockets Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
(HFA-305), Rockville, MD 20852, USA

**Re.: Compliance Guidance "The Mammography Quality Standards Act Final Regulations" - Document #4 - Draft released for comment on September 13, 2000**

With reference to the above draft guidance we would like to transmit our comments about the following subject:

**Equipment**

**21 CFR 900.12(b)(8)(i)**

*Application of compression. Effective October 28, 2002, each system shall provide: (A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and (B) Fine adjustment compression controls operable from both sides of the patient.*

Question: A system as GIOTTO HT (IMS) which has (A) an initial power-driven compression activated by a foot pedal (as an alternative, there is also a hand control mounted on the compression device, operable in front of the patient) and (B) a fine adjustment power-driven compression activated by a foot pedal, can meet the above requirement? Since the mechanism of GIOTTO HT is similar to that of GE 600T, are we covered by the ruling published in the draft guidance in object, regarding GE500T and GE600T?

Hoping that you will consider our question, we thank you in advance.

Best regards,

IMS Internazionale Medico Scientifica s.r.l.  
Antonella Rossi, QA

Cap. Soc. 1.300.000.000 i.v.  
Registro Imprese Bologna n. 31898  
C.C.I.A.A. Bo 265298  
Cod. Fisc. 03117190375  
Part. IVA - VAT IT00597211200

00D-1497

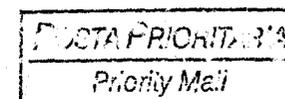
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VIA SAGITTARIO, 5  
40044 PONTECCHIO MARCONI  
SASSO MARCONI - BOLOGNA - ITALY  
TEL. 051/84.68.51 (R.A.)  
FAX 051/84.68.56  
E-mail: imscomm@tin.it - imstech@tin.it



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