To Whom It May Concern:

As per Occupational Safety and Health Authority (OSHA) Standard (29 CFR § 1910.1200), Material Safety Data Sheets (MSDS) are required for products containing a hazardous material greater than or equal to 1% of the composition, or a carcinogen greater or equal to 0.1% of the composition.

The following products are considered non-hazardous by this standard:

- Heparin Assay - Red Cartridge
- Heparin Assay - Yellow Cartridge
- Heparin Assay - Tan Cartridge
- Heparin Assay - Silver Cartridge
- Heparin Assay - Blue Cartridge
- Heparin Assay - Green Cartridge
- Heparin Assay - Orange Cartridge
- Heparin Assay - Gold Cartridge
- Heparin Assay - White Cartridge
- Heparin Assay - Purple Cartridge
- Heparin Assay - Black Cartridge
- Heparin Dose Response Cartridge
- HR ACT Cartridge
- Red/Yellow Control
- Tan/Silver Control
- Blue/Gold Control
- Green/White Control
- Orange Control
- Purple/Black Control
- LR-ACT Cartridge
- RACT Cartridge
- HR-ACT Cartridge
- HTC Cartridge
- CLOTtrac CWB Control
- CLOTtrac HR Control
- CLOTtrac HR Abnormal Control
- CLOTtrac LR Abnormal Control
- CLOTtrac RACT Abnormal Control
- Calcium Chloride
- CLOTtrac HTC Control
- CLOTtrac Control Pack
- HEPlne Kit

Proficiency Kits: Catalog Numbers 550-90, 550-91, 55091A(CT1-01 thru 06 and CT5-01 thru 06), 55091B (CT1-01 thru 06 and CT5-01 thru 06), 55092, 55093, 55095, 55096, 55097
Specifics on controls:

Medtronic controls have no human derived components, thus there is no risk from human infectious diseases. The transmission of infectious material of sheep origin is extremely remote. The sheep used to manufacture Medtronic Perfusion System coagulation controls are a controlled flock of sheep that are maintained strictly for the purpose of providing blood for the manufacture of controls. These sheep are drawn under controlled conditions, their diet controlled, and each individual sheep carries an identification ID. The sheep's general physical conditions are monitored regularly, and the coagulation characteristics and hematocrits monitored.

During the processing of the blood into various controls, the cellular components are isolated and then run through a process that fixes the cell membrane. This process inactivates viral, bacterial, or parasitic contaminants that could be present in the cellular fraction. The cells are then washed and added back to the plasma. Coagulation controls do not undergo any sterilization procedures, since sterilization would destroy the coagulation activity of the control. Fresh, frozen, and lyophilized whole blood and plasma are used on nearly a daily basis since 1984. During this period of time, there have been no adverse affects reported or identified with respect to any biological interactions with sheep blood.

Please refer to the product package inserts for information regarding ingredients and proper handling. If you have any further questions or for any additional information, please call me at (303) 840-4012.

Sincerely,

[Signature]

Suzan Dillon
Manufacturing Manager
Medtronic Structural Heart