

To whom it may concern

**MATERIALS OF CONCERN DECLARATION**

METACROSS® RX PTA Balloon Dilatation Catheter
METACROSS® OTW PTA Balloon Dilatation Catheter
R2P™ METACROSS® RX PTA Balloon Dilatation Catheter
CROSSTELLA® RX PTA Balloon Dilatation Catheter
CROSSTELLA® OTW PTA Balloon Dilatation Catheter
R2P™ CROSSTELLA® RX PTA Balloon Dilatation Catheter
CROSPERIO® RX PTA Balloon Dilatation Catheter
CROSPERIO® OTW PTA Balloon Dilatation Catheter
RX TAKERU™ PTCA Balloon Dilatation Catheter
OTW TAKERU™ PTCA Balloon Dilatation Catheter
RX NC TAKERU™ PTCA Balloon Dilatation Catheter

Please be advised that the above medical devices manufactured by KANEKA CORPORATION and distributed by TERUMO MEDICAL CORPORATION do not contain the following compounds:

BPA	Heparin
Murine Antibody	Albumin
Swine Aortic Valve	Urokinase
Swine Cardiac Valve	Hyaluronic acid
Equine Pericardial Membrane	Casein
Bovine Pericardial Membrane	Vitamins
Silver Protein (or Silver Protainate)	PVC
Ovine Antibody	Mercury
Collagen	DEHP** Di (2-ethylhexyl) phthalate

\*\* DEHP is known by many other chemical names in the industry. Please cross reference the following list:

1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester; Octoil; Ethyl hexyl phthalate; 2-Ethylhexyl phthalate; bis(2-ethylhexyl) 1,2-benzendicarboxylate; octyl phthalate; phthalic acid dioctyl ester; BEHP; bisoflex 81; bisoflex dop; compound 889; DAF 68; ergoplast fdo; eviplast 80; eviplast 81; fleximel; flexol dop; flexol plasticizer dop; good-rite gp 264; hatcol dop; hercoflex 260; kodaflex dop; mollan o; nuoplaz dop; palatinol ah; Pittsburgh px 138; platinol ah; platinol dop; rc plasticizer dop; reomol dop; reomol d 79p; sicol 150; staflex dop; truflex dop; vestinol ah; vinicizer 80; witicizer 312; Benzenedicarboxylic acid; bis(2-ethylhexyl) ester; Union carbide flexol 380.

Sincerely,

Signature:           K. Sanaka          

Name: Kazuaki Sanaka

Title: QMS Management Representative