MATERIALS OF CONCERN DECLARATION

| METACROSS® RX PTA Balloon Dilatation Catheter |
| METACROSS® OTW PTA Balloon Dilatation Catheter |
| RZP™ METACROSS® RX PTA Balloon Dilatation Catheter |
| CROSSTELLA® RX PTA Balloon Dilatation Catheter |
| CROSSTELLA® OTW 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  
Murine Antibody  
Swine Aortic Valve  
Swine Cardiac Valve  
Equine Pericardial Membrane  
Bovine Pericardial Membrane  
Silver Protein (or Silver Protainate)  
Ovine Antibody  
Collagen  
Heparin  
Albumin  
Urokinase  
Hyaluronic acid  
Casein  
Vitamins  
PVC  
Mercury  
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-benzenedicarboxylate; octyl phthalate; phthalic acid dioctyl ester; BEHP; bisoflex 81; bisoflex dop; compound 889; DAF 68; ergoplant fdo; eviplast 80; eviplast 81; flexime1; flexol dop; flexol plasticizer dop; good-rite gp 264; hatcol dop; hercosh 260; kodaflex dop; mollon 0; nuoplaz dop; palatinol ah; pittsburgh px-138; platinol ah; platinol dop; re plasticizer dop; reomol dop; reomol d 79p; sicol 150; staflex dop; truflex dop; vestinol ah; vinicizer 80; witecizer 312; Benzenedicarboxylic acid; bis(2-ethylhexyl) ester; Union carbide flexol 380.

Sincerely,

Signature: K. Sanaka

Name: Kazuaki Sanaka

Title: QMS Management Representative

Date: 2018-04-04