



KANEKA CORPORATION

2-3-18, NAKANOSHIMA, KITA-KU, OSAKA 530-8288, JAPAN
Tel (06) 6226-5256 Fax (06) 6226-5143

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
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; wtcizer 312; Benzenedicarboxylic acid; bis(2-ethylhexyl) ester; Union carbide flexol 380.

Sincerely,

Signature: K. Sanaka

Name: Kazuaki Sanaka

PM-00879

Title: QMS Management Representative

Date: 2018-04-04