

Osaka, 5 April 2021

To whom it may concern

LATEX DECLARATION

We, KANEKA CORPORATION, Japan, being the manufacturer of the following products hereby declare that:

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

- that above mentioned device and its packaging do not contain components made with natural rubber latex.
- that during the production of the above mentioned product no natural rubber (latex), and no natural rubber (latex) containing parts, have intentionally been used.
- that during the manufacturing process of the above mentioned product, no natural rubber (latex) gloves have been worn.
- that the possible presence of ubiquitous traces, of natural rubber (latex), can of course never be totally ruled out.

Sincerely,

Signature: _____



Name: Kazuaki Sanaka

Title: QMS Management Representative