TERUMO MEDICAL CORPORATION
REGULATORY AFFAIRS
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Date: 9/14/2018

We, TERUMO Medical Corporation, being the manufacturer of the following products hereby declare:

LATEX DECLARATION

PINNACLE® Introducer Sheath	GLIDESHEATH™ Introducer Sheath
PINNACLE® TIF TIP™ Introducer Sheath	GLIDEACCESS® System
PINNACLE® R/O II HiFlo Introducer Sheath	DESTINATION® Guiding Sheath
PINNACLE® R/O II Radiopaque Marker Introducer Sheath	R2P™ DESTINATION SLENDER™ Guiding Sheath
PINNACLE PRECISION ACCESS SYSTEM® Sheath	SOLOPATH® Balloon Expandable TransFemoral System
RADIFOCUS® Introducer Sheath	SOLOPATH® Re-collapsible Balloon Access System
RADIFOCUS® R/O II Introducer Sheath	ANGIO-SEAL® Vascular Closure Device
RADIFOCUS® R/O II HiFlo Introducer Sheath	FEMOSEAL® Vascular Closure Device
GLIDESHEATH SLENDER® Introducer Sheath	TRBand® Radial Compression Device
GLIDESHEATH SLENDER® Tibial Pedal Introducer Sheath	

- the above mentioned devices and their packaging do not contain components made with natural rubber latex.
- during the manufacturing of the above mentioned products no natural rubber (latex), and no natural rubber (latex) containing parts, have intentionally been used.
- during the manufacturing of the above mentioned products, no natural rubber (latex) gloves have been worn.
- the possible presence of ubiquitous traces of natural rubber (latex) can of course never be totally ruled out and may be present.

Sincerley,

John Boselli
Sr. VP of Quality and Regulatory Affairs