



PulseCath B.V.

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Statement

to: All interested

of: Louis Habets
PulseCath RaQa Manager

date: 10 April 2019

Project / Ref.: 3387

subject: Latex Free status of iVAC 2L

No Latex Statement for PulseCath iVAC 2L

A declaration of "Latex Free" is not part of the requirements provided in the European Medical Device Directive (EU DIR 93/42/EEC). However, it can be stated that PulseCath does not use Latex in the production process of the iVAC 2L catheter or its parts and components.

Please be informed that PulseCath relies on information provided by its suppliers and vendors, whose materials make up the content of the products. None of the Material Data Sheets that were provided to PulseCath indicate the use or existence of Latex.

Date of compilation:

- date: 10 April 2019
- by: A.L.M. Habets

A handwritten signature in blue ink, appearing to read "A.L.M. Habets".

RaQa Manager
PulseCath B.V.