



# Policy Statement - Natural Rubber LATEX

## Background:

Natural Latex and vulcanised rubber containing traces of natural rubber latex are used in a number of medical applications. Type 1 and Type 4 sensitivities to Natural Latex have been reported from single and chronic exposure.<sup>1, 2</sup>

## Statement:

Rocket Medical plc. is aware of the risks of latex exposure and therefore manufactures the vast majority of its products without the use of natural rubber latex or materials which contain natural rubber latex. However, there are no analytical methods currently available that can identify all proteins and components in natural rubber latex that may lead to allergic reactions in medical product users. In addition, the use of the term “free” or “does not contain” does not address the potential for accidental contamination of a medical product and/or its container with natural rubber latex during or after manufacturing.<sup>3</sup>

Therefore, in line with the recommendations of the UK Department of Health<sup>2</sup>, UK Health & Safety Executive<sup>1</sup> and in accordance with the Guidelines provided by the US Food & Drug Administration<sup>3</sup> Dec. 2014:

Unless specifically labelled as containing latex, all Rocket<sup>®</sup> products and packaging can be considered as having been manufactured *without* the use of natural rubber latex.

In addition and where appropriate, product labelling will carry this symbol for clarification:



Where contained, the product 'Instructions for Use' will carry the symbol and additional explanation:

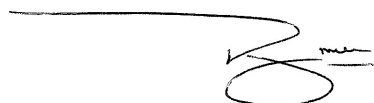


Rocket products which are known to contain natural rubber latex are normally reserved for specialist applications. These products have additional and specific labelling citing relevant warnings and cautions appropriate to latex exposure in line with current recommendations and guidelines.<sup>1,2,3</sup>

## References:

1. Health & Safety Executive: Natural rubber latex sensitisation in health and social care: SIM 07/2011/06
2. Department of Health. HSC1999/186 'Latex medical gloves and powdered latex medical gloves: reducing the risk of allergic reaction to latex and powdered medical gloves
3. Recommendations for Labelling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex; Guidance for Industry and Food and Drug Administration Staff . 02/12/14.

For and on behalf of Rocket Medical plc.



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