

DECLARATION

To whom it may concern

Medical devices are exempted of Material Safety Data Sheet (MSDS) as:

- 67/548/EEC not apply for medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC.
- Title IV of REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), not apply for medical devices which are invasive or used in direct physical contact with the human body in so far as Community measures lay down provisions for the classification and labelling of dangerous substances and preparations which ensure the same level of information provision and protection as Directive 1999/45/EC;

Seawater as a natural substance is also exempted of Material Safety Data Sheet (MSDS) as:

- Non-classified as dangerous according to the directives 67/548/CEE,
- Non-toxic according to the criteria expressed in the appendix XIII of the directive REACH,
- Non-included in the list of substances proposed for an eventual inclusion in the appendix XIV of the directive REACH (substances submitted to authorization).

For all pertinent purposes, I hereby sign this document in Barcelona, on 21st of November 2018,

A blue ink signature of Rafael Martínez is written over the PharmaLink logo and company information.

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Qualified Person