SINCE 1966
FLAEMNUOVA S.p.A.
HEALTHCARE & HOUSEHOLD PRODUCTS

FLAEM NUOVA S.p.A.
Via Colli Storici, 221-223-225 - 25015 S. Martino della Battaglia (BS) Italy
Tel. +39 030 9910168 - Fax +39 030 9910287
info@flaemnuova.it - www.flaemnuova.it

PRODUCT TRACEABILITY CIRCULAR LETTER

Dear Customer,

We are certain that you are already aware of this development, but we need to highlight it because of its importance: both the MDD Directive 93/42 and the new MDR (EU) Regulation 2017/745 require the establishment of a traceability system for medical devices placed on the market.

Specifically, article 14 of the new regulation establishes a series of obligations for distributors - the last paragraph of the article reads as follows: "*Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market*" and "*on **any action taken to eliminate the risks posed by devices which they have made available on the market***. *Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, **grant access** to the device*".

FLAEM has, for quite some time, adopted a system for the identification of devices and keeps proof of traceability until the sale document (the recipient of the transport document that accompanies the goods that exit the factory).

It is necessary that this product traceability logic continues all the way to the end user (the consumer): this will only be possible thanks to your cooperation, by your keeping records that constitute a further link in the distribution chain.

Please remember that the traceability requirement is necessary to trace, with certainty and promptly, the recipients and the end users of the products involved in a recall, in the unfortunate event that there should be a recall of batches of defective or potentially defective devices, as envisaged by the MEDDEV 2.12-1 guidance (latest revision) and by the Italian Ministerial Decree of 15 November 2005.

We would like to thank you in advance for the attention with which you will read this letter and for your cooperation in the establishment of this chain of traceability.

Best regards