**Client**

**Contact**

Adresse

St Priest, Octobre 24, 2017

**Object:** Inventory Request

**Commercial name of the medical device:** HEMOSNOW™, COVA+™, MATRIBONE™

**Commercial reference:** HEM03C, COV+68, MAB11Bb

**Manufacturer:** Biom'up

Madam, Sir,

The purpose of this letter in to inform you that Biom'up has decided to set up a voluntary corrective action following internal discrepancies in its computerized traceability system (ERP).

Indeed, as part of our inventories (counting of physical products and reconciliation with computer inventories), we have highlighted a discrepancy in the quantities collected. This discrepancy may also involve the tracking of certain products that may have been shipped to you.

Your institution has been identified in our system as a recipient of one or more of the product(s) concerned. Three ranges of devices are affected by this irregularity: HEMOSNOW™, COVA+™ and MATRIBONE™. Please find enclosed (Annex 1) the list of the batches concerned.

Please be assured, there is no problem with any of the distributed medical devices - all have passed final release testing and are properly labeled. The problem is related solely to tracking their distribution. Incomplete traceability is a quality system issue and we are appropriately addressing it to ensure it does not occur in the future via our Corrective & Preventive Action system.

Based on the data available, Biom'up confirms that:

- The devices meet all quality assurance release specifications.

- No patient risk has been identified

- The products can be used without restriction according to their claimed use / indication.

**Actions required by the health facility:**

In order to correct this discrepancy, we kindly ask you to carry out a **physical inventory of the products** listed in Appendix 1 that **you have in stock or that have been implanted**.

We kindly ask you to return the data of this inventory within **15 days** after reception of this letter by returning the voucher available in Annex 2.

I would like to inform you that the ANSM (French Competent Authority) and your competent authority have been notified.

We take very seriously the problems of traceability of our products and all corrective measures will be taken to prevent this problem from recurring.

I would be pleased to answer any questions you may have on this file and I would like to extend my greetings to you.

Marine ROUYER

Vigilance Manager

regulatoryaffairs@biomup.com

## ANNEX 1 : LIST OF PRODUCTS CONCERNED

| DEVICE NAME | REFERENCE | BATCH |
|---|---|---|
| HEMOSNOW™ | HEM03C | SPR17001.133764 |
| HEMOSNOW™ | HEM03C | SPR17002.133767 |
| COVA+™ | COV+68 | MCG15006.133407 |
| COVA+™ | COV+68 | MCG16002.133832 |
| MATRIBONE™ | MAB11Bb | EPM16023.133721 |
| MATRIBONE™ | MAB11Bb | EPM16023.133834 |

## ANNEX 2 : VOUCHER AND INVENTORY

**PLEASE RETURN A FILLED COPY RATHER:**

**By email: regulatoryaffairs@biomup.com**

**By Fax: 04 37 69 00 84**

Establishment : _____

Address : _____

I certify to have reviewed and understood the content of this letter.

☐ I have checked my stock and collected data are listed in the table below:

| DEVICE NAME | REFERENCE | BATCH | QTY RECEIVED | QTY IMPLANTED | REMAIN STOCK |
|---|---|---|---|---|---|
| HEMOSNOW™ | HEM03C | SPR17001.133764 | | | |
| HEMOSNOW™ | HEM03C | SPR17002.133767 | | | |
| COVA+™ | COV+68 | MCG15006.133407 | | | |
| COVA+™ | COV+68 | MCG16002.133832 | | | |
| MATRIBONE™ | MAB11Bb | EPM16023.133721 | | | |
| MATRIBONE™ | MAB11Bb | EPM16023.133834 | | | |

Date: _____

Name: _____

Position: _____

Signature: _____

Email: _____

Stamp: