M-821-02 Rev. 00 del 30/04/2020

Ospedalicchio, [date]

Attn. QUALITY AFFAIRS DEPARTMENT

To the kind attention of the QA/RA Manager

Dear Sir/Madam:

According to the 93/42/EEC Directive, BETATEX S.p.A., as manufacturer, must ensure the complete traceability of all marketed devices and appropriate market surveillance activities.

In order to guarantee these requirements, the traceability procedures must be applied to the entire product distribution chain, up to the final customer. In this regard, we kindly ask for your cooperation to ensure the correct traceability of the devices at the end customer, in order to comply with specific obligations imposed by the current legislation.

BETATEX reserves the right to directly verify the correct application of your batch traceability procedures by means of suitable quality audits or other checks, even by telephone only.

If we do not receive the attached declaration filled in and signed, in case an adverse event occurs (in accordance with Legislative Decree 46/97 and subsequent amendments) your Company will be required to withdraw all product batches from the market.

Regarding post-market surveillance activities, we kindly ask for your cooperation in relation to our products distributed through your company. We therefore ask you to engage in collecting and reporting to BETATEX the data and information from the market about any adverse event (according to the definition of Directive 93/42 / EEC and subsequent amendments and of the MEDDEV 2.12-1, current edition) that may occur in the use of our products in your country, in order to report to the Competent Authority.

We therefore ask you to fill in the attached form and send it us back as soon as possible.

Thank you in advance for your kind cooperation,

Best regards,

BETATEX S.p.A.

Quality Department

BETATEX Spa
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Sede Produttiva e Commerciale:
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Spett. **BETATEX SPA**

At care of Quality

Department Date: 01/07/2020

The undersigned.....VERENDEANU IONEL...as the legal representative of the Company...L&P MEDICAL SRL,located in TIMISOARA-ROMANIA hereby declare under my own responsibility that:

1. **A procedure has been put in place that enables us to record all the destinations for any batch of devices supplied by BETATEX S.p.A., according to the 93/42/EEC directive.**

   We also declare that, whenever requested, the company will be able to provide the following information concerning a specific batch of products:

   - Delivery date to the final customer
   - Final customer name and address
   - Product batch number
   - Quantity delivered to the final customer

2. **All the requirements above have been applied to the third parties involved in re-selling BETATEX products, whenever applicable;**

3. **We will actively co-operate with BETATEX S.p.A in reporting any adverse event (incidents, according to the definition of Directive 93/42 / EEC and subsequent amendments and of the MEDDEV 2.12-1, current edition) that may occur in the use of BETATEX products in our Country.** I agree to make the reporting of any adverse event at the Competent Authority and handle all subsequent communication, in behalf of BETATEX S.p.A., which remains responsible for managing the requested activities for the solution of any adverse event.

4. **We will communicate to BETATEX any information concerning any anomaly or deterioration or alteration of the medical device features.**

5. **All the documents necessary to ensure compliance with points 1, 2 and 3 above will be kept for a period of 10 years since the manufacturing date of the last purchased lot.**

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6. **The products will be stored in dry and clean areas, away from sunlight and heat sources, in compliance with the storage conditions indicated on the packaging.**

7. **We will not alter in any way the labelling and primary/secondary packaging of devices, without prior verification and approval by BETATEX.**

This declaration supplements the agreement between our companies for all BETATEX's products.

In good faith,

RO 42026251; J35/4594/2019
L&P MEDICAL S.R.L.
TIMIȘOARA, ROMANIA

VERENDEANU IONEL

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