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Auto Ribeiro Lda

AUTHORIZED REPRESENTATION AGREEMENT

Digitally signed by Gorgan Vasile-Dan
Date: 2024.09.17 10:38:48 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

This Agreement shall be concluded between:

Auto Ribeiro, Lda
Rua de São Caretano Nº 456/519
4410-949 Canelas VNG

Phone: +351 227 157 100
Email: geral@autiribeiro.com
NIF/EORI: PT500434980

as **Manufacturer** and

DELTAMED NOVA SRL, based in MD-2012, str. Alexndru cel Bun, nr. 49, mun. Chisinau, Republic of Moldova, having state identification number and fiscal code (IDNO): 1020600047239, bank account no. MD50VI022240300001102MDL, opened at BC "VictoriaBank" SA Branch 3 Chisinau, represented by Mr. Gorgan Vasile Dan, administrator, as **Authorized Representative**

Whereas the Authorised Representative:
• has its registered office in the Republic of Moldova
• is willing to assist the manufacturer as an authorized representative in the area for contacts between the manufacturer and the authorities of the Republic of Moldova
• will act as a communication channel and contact point for the authorities of the Republic of Moldova and for the Manufacturer, on issues of compliance with the regulations regarding medical devices produced by the manufacturer and placed on the market in the Republic of Moldova

Have agreed the following, with regard to the safe handling of medical devices (hereinafter referred to as "Products") manufactured and supplied by the Manufacturer to the Authorised Representative in order to comply with the requirements contained in the *Medical Device Vigilance System (hereinafter referred to as the "Guidelines").*

The Manufacturer hereby appoints Deltamed Nova, under the terms and conditions contained in this Agreement, as **Official Representative** for the products manufactured by the Manufacturer, given that Deltamed Nova expresses its desire to conclude an agreement with the Manufacturer under the terms and conditions set forth in this Agreement.

Terms:
• Deltamed Nova is and will remain an independent contractor and is not and will not be considered to be an employee, joint venture or franchisee of the Manufacturer
• The services of the Authorized Representative shall be provided only for medical devices provided by the Manufacturer and under this agreement.

Responsibilities of the parties:
Deltamed Nova is authorized to carry out the registration, renewal and modification of the registration of medical devices.

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The manufacturer shall provide the Authorised Representative for the registration of medical devices with the following information:
(a) declaration of conformity
(b) a copy of the label, packaging and instructions for use (in all languages required by the countries in which the device is marketed),
(c) notified body certificates (if applicable),
(d) the post-market surveillance process and data, vigilance reports and complaints, processes and data;
(e) technical documentation relevant to the market surveillance investigation conducted by the Medicines and Medical Devices Agency (Agency);
f) relevant clinical data/notifications;
g) details of possible distributors/suppliers placing on the market devices marked by the Republic of Moldova;
h) incident reports and reports on corrective actions taken.

The Authorized Representative shall be responsible for registering, monitoring and communicating all customer complaints regarding the products supplied by the Manufacturer and notifying him of the receipt of such complaints.

Incident reporting

The authorised representative shall maintain an up-to-date quality system and communicate vigilance procedures to the manufacturer to ensure coordination and continuity of his own quality system. It will also communicate any other procedures requested, at the request of the Manufacturer.

The Authorized Representative shall communicate closely with the Manufacturer and shall transmit without delay any information coming from the Agency. In case of a special request from the Agency, in particular in relation to incident reporting, the Authorised Representative shall agree with the Manufacturer on the position to be taken and the replies to be addressed to the Agency.

In case of difference of positions between the Manufacturer and the Authorised Representative, the position of the Manufacturer shall prevail and the information shall be provided to the Agency only in the form approved by him.

Deltamed Nova will appoint a qualified person to liaise with the Agency.

In case of incidents first brought to the attention of the Manufacturer, the Authorized Representative shall be informed immediately and shall immediately carry out with the Manufacturer the analysis of the incident.

The authorised representative shall write and send to the Agency the initial report including available actions, such as: analysis of samples, analysis of historical batch records and potential corrective actions to be taken in further handling of the product, such as withdrawal or recall from the market.

Deltamed Nova will notify the Agency of the following deadlines that will apply in case of incidents, as follows:

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a) in case of serious threat to public health: **IMMEDIATELY** (without any delay that could not be justified), **but no later than 2 calendar days** from the date of acknowledgement by the Manufacturer of this threat;

b) in case of death or unanticipated serious deterioration of health: **IMMEDIATELY** (without any delay that could not be justified) after the Manufacturer has established a link between the device and the event, **but no later than 10 calendar days from the date** of acknowledgement by the Manufacturer of the event;

c) other: **IMMEDIATELY** (without any delay that could not be justified) after the Manufacturer has established a link between the device and the event, **but no later than 30 calendar days** from the date of acknowledgement by the Manufacturer of the event.

If, after becoming aware of a potential reportable incident, there is still uncertainty as to whether the event is reportable or not, the Manufacturer shall submit a report stating the required timeframe in relation to the type of incident that occurred.

As soon as information and incident assessment from the Manufacturer are available, the Authorised Representative shall prepare and submit the final incident report. All reports will be submitted to the Manufacturer for prior approval. The manufacturer shall keep records at the disposal of the Agency.

According to the provisions of the Guidelines, the Manufacturer shall present a summary of the manufacturing process of the products and shall take appropriate measures if he becomes aware of the occasional occurrence of any incident concerning the medical device produced, such as: degradation of medical equipment or its improper use, without consulting the user manual that may lead to death of patients and users or deterioration of health. In these situations, the Manufacturer has the right to recall products placed on the market and belonging to the same batch.

Field Safety Notice

If the Manufacturer finds that there is a quality problem with the products placed on the market, it will immediately issue a field safety notice to users so that they can take the necessary and appropriate measures (including product withdrawal).

Recall/withdrawal

If products are withdrawn from the market, the manufacturer must immediately recall the products. Before recalling the products, the Authorised Representative shall inform the Agency.

Returning products to the Manufacturer

The Manufacturer will send a notification to the Authorized Representative in the region ordering to stop selling problematic products, recall products sold and inform users, as well as inform local authorities.

After the Authorized Representative recalls the products, the Manufacturer shall agree with him on the method of transport and the deadline for returning the products, in order to remove them from the market.

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Traceability of products sold

The manufacturer keeps records of serial numbers, batch numbers for all products delivered to the Authorized Representative.

Authorized representative will keep records of Products delivered to users or distributors. In this case, traceability of the products sold can be carried out at any time, upon request.

The records shall include the following information:

- name and address of the customer
- the quantity dispatched,
- date of transfer to the client
- serial numbers of production batches

These records will be available for inspection at the request of the Manufacturer or competent authorities.

Technical documentation

The manufacturer shall establish the necessary procedures for the preparation and preparation of technical documentation, including the Declaration of Conformity, for manufactured products, as required by the Guidelines.

The manufacturer shall transfer the approved technical documentation and declaration of conformity to the Authorised Representative, who shall keep them at the disposal of the Agency for at least five years after the sale of the last products. The manufacturer shall provide the Authorised Representative with additional documentation if requested by the Agency.

Manual

The manufacturer shall be responsible for the content of the instruction manual (user guide) and shall ensure the availability of the English version of the instruction manual for the Authorised Representative.

The authorized representative shall provide the necessary instruction manuals to be provided to the customer in the official language of the Republic of Moldova.

Product categories/product group and model(s) are:
M860 RO / CLASS I

Duration of the agreement

This Agreement enters into force on the date of its signature by both parties and will have a duration of 5 years, with automatic extension, for the same period, if neither party requests its termination, 30 days before the expiration date.

Termination of Agreement

Material infringement for the purposes of this section includes, but is not limited to:

(a) failure by the Manufacturer to provide the necessary information and/or assistance to the Authorised Representative

(b) failure of the Manufacturer to meet the requirements of national legislation relating to manufactured medical devices.

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In these cases, the agreement may be terminated immediately by one of the parties, by giving written notice to the other party at least (30) days, indicating the reasons for termination.

Reasonable grounds will be deemed to exist if circumstances would make it unreasonable for defaulters to continue performing the agreement, including one or more of the following events:
• the other party fails to promptly remedy a material breach of this Agreement no later than thirty (30) days after notice reasonably specifying the breach and/or fails to remedy the consequences of such breach.
• the other Party refuses to cooperate in a manner that makes performance by the non-defaulting Party under this Agreement unsustainable;
• the other party ceases to carry out activities normally; becomes insolvent; makes a general assignment for the benefit of creditors; engage in fraudulent transfers.

This Agreement was concluded today **07/06/2024** in duplicate, one for each Party.

Manufacturer

Auto Ribeiro Lda.
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4411-701 Canelas, VNG
NIF: 500 434 980

Authorised Representative
DELTAMED NOVA SRL
by adm. Vasile Dan Gorgan