## Letter of Designation

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| Party A (Manufacturer) | Party B(UK responsible person): **Umedwings UK LTD** |
| Add: Tel: E-mail: | Add:291 Brighton Road, South Croydon, United Kingdom, CR2 6EQTel: +44 7516 043398 E-mail: ukrp@umedwings.uk |

According to Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002),
to place a device on the Great Britain market (England, Wales and Scotland), manufacturers based outside the UK are required to appoint a UK Responsible Person. The UK Responsible Person acts on behalf of the non-UK manufacturer to carry out specified tasks in relation to the manufacturer’s obligations,includes registering the manufacturer’s devices with the MHRA before the devices can be placed on the Great Britain market.

In addition to the registration requirements, the UK Responsible Person must:

1. ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer
2. keep available a copy of the technical documentation, a copy of the declaration of 4, if applicable, a copy of the relevant certificate, including any amendments and supplements for inspection by the MHRA
3. in response to a request from the MHRA, provide the MHRA with all the information and documentation necessary to demonstrate the conformity of a device
4. where they have samples of the devices or access to the device, comply with any request from the MHRA to provide such samples or access to the device
5. where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the MHRA to provide such samples or access, and communicate to the MHRA whether the manufacturer intends to comply with that request
6. cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices
7. immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed
8. if the manufacturer acts contrary to its obligations under these Regulations:

terminate the legal relationship with the manufacturer;

And inform the MHRA and, if applicable, the relevant Approved Body of that termination.

The name and address of the UK Responsible Person, where applicable, must be included on the product labelling or the outer packaging, or the instructions for use in cases where the UKCA marking has been affixed. UK Responsible Person details do not need to be included on labelling for CE marked devices, unless the device bears both the CE and UKCA markings.

Party A (manufacturer) hereby designates Party B as the UK responsible person (UKRP) for their devices bearing UKCA marking and Party B accepts the designation to be the UK responsible person (UKRP) for the devices on the market of United Kingdom:

**List of generic device group(s) covered by this Designation**

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| **NO.** | **Product Description** | **Model** | **Class** | **GMDN** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |

Start date of Designation:*June X, 2022*

End date of Designation:*June X, 2027*

EXECUTED by the parties below:

|  |  |
| --- | --- |
| **Manufacturer：** | **UK Responsible Person：****Umedwings UK LTD**  |
| Add： | Add: 291 Brighton Road, South Croydon, United Kingdom, CR2 6EQ |
| Tel： | Tel： +44 7516 043398  |
| E-mail： | E-mail：ukrp@umedwings.uk |