

## DECLARATION

Subject: NON-MEDICAL DEVICE DECLARATION

We, Bionet Declare that the following supply items are non-medical devices.

[Standard for not classifying medical devices]

The following supply items are not included in the definition of 'medical device' and 'accessory'

- The following supply items are not included in the definition of 'medical device'. (annex.1)
- It does not harm the human body
- Power supply part (battery)
- Components for connecting the medical accessories
- Accessories for veterinary use only

(ANNEX.1)

| GIMA CODE | REFERENCE CODE | DESCRIPTION  | ORIGIN COUNTRY | MANUFACTURER | MEDICAL DEVICE - YES OR NOT | CLASS |
|-----------|----------------|--|----------------|--------------|-----------------------------|-------|
| 29519     | 120108-048900  | TROLLEY (Cart FM)                                  | Korea          | Camtes       | NO                          | X     |
| 29522     | 152600-000800  | FOETAL MONITORS THERMAL PAPER ROLL - 215 mm x 23 m | Korea          | Yusungchart  | NO                          | X     |
| 29525     | 152600-000300  | BELT - 5.3 x 148 cm                                | Korea          | Cubein       | NO                          | X     |
| 29534     | 151900-010100  | Ni-MH 12V BATTERY                                  | China          | BN-Tech      | NO                          | X     |
| 29536     | 151900-009032  | BATTERY  | China          | BN-Tech      | NO                          | X     |
| 33304     | 151900-044300  | BATTERY Li-Ion - 111 V - 4400 mAh                  | Korea          | BN-Tech      | NO                          | X     |
| 33362     | 152600-016000  | DISPOSABLE MOUTHPIECES - box of 100 pcs            | Korea          | CK-Tech      | NO                          | X     |
| 33715     | 151900-009200  | BATTERY Ni-MH 12V                                  | China          | BN-Tech      | NO                          | X     |



## Bionet Co., Ltd.

5F, 61 Digital-ro 31-gil Guro-gu, Seoul. 08375 Republic of Korea

TEL: +82-2-6300-6410

FAX: +82-2-6499-7766

|       |               |  |       |             |    |   |
|-------|---------------|--|-------|-------------|----|---|
| 33716 | 152600-004002 | SpO2 EXTENTION CABLE* - 2 m - 7 pin              | Korea | Mednis      | NO | X |
| 33717 | 151900-009001 | BATTERY Li-ion 10.8V                             | Korea | BN-Tech     | NO | X |
| 33725 | 120108-048800 | BM3 - BM5 - BM7 CART/TROLLEY - adjustable height | Korea | Camtes      | NO | X |
| 33732 | 152600-003300 | VETERINARY REUSABLE SpO2 PROBE - clip            | Korea | Mednis      | NO | X |
| 33738 | 152600-022401 | NIBP EXTENSION CABLE - 3 m                       | Korea | Mi-Rae Tech | NO | X |
| 33739 | 152600-004400 | METAL CONNECTOR (necessary for mini cuff)        | Korea | Mi-Rae Tech | NO | X |
| 33742 | 151900-009100 | BATTERY Ni-MH 12V                                | China | BN-Tech     | NO | X |
| 33743 | 152600-007000 | THERMAL PAPER - 57.5 mm, Ø 38 - for monitors     | Korea | Yusungchart | NO | X |
| 33752 | 152600-021200 | VET 3-LEAD CLIP TYPE CONNECTORS                  | Korea | Mednis      | NO | X |
| 33753 | 152600-021700 | VET 5-LEAD CLIP TYPE CONNECTORS                  | Korea | Mednis      | NO | X |
| 33760 | 152600-002200 | VET 3-LEAD CLIP TYPE CONNECTORS                  | Korea | Mednis      | NO | X |
| 33761 | 152600-002700 | VET 5-LEAD CLIP TYPE CONNECTORS                  | Korea | Mednis      | NO | X |
| 33766 | 152600-024500 | 3-LEAD VETERINARY CABLE KIT                      | Korea | Mednis      | NO | X |

Date: March 17, 2022

Chuelwon Lee  
RA manager