This is an example on how electronic IFU will be accessed

Information below will be in Ukrainian language

Instruction for use of the medical device

EXAMPLE®

REF ABC0123

Product description.

The details strictly necessary to identify the device and the contents of the packaging especially for the users.

Where appropriate, an indication that the device is for single use.

Any special storage and/or handling conditions.

Any special operating instructions.

Any warnings and/or precautions to take.

Any undesirable sideeffects.

If the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination.

All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times.

Where appropriate, information to avoid certain risks in connection with implantation of the device.

Information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment.

The necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization.

If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.

Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.).

In the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:

Precautions to be taken in the event of changes in the performance of the device.

Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.

Adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;

Precautions to be taken against any special, unusual risks related to the disposal of the device.

Medicinal substances, or human blood derivatives incorporated into the device as an integral part.

Degree of accuracy claimed for devices with a measuring function.

Example manufacturer Inc.
Example str. 1, Save Planet District, Rational city, 01001
Futureland

Name of the Authorized representative in Ukraine:
Cratia Medtekhnika LLC
17-21 Baggovutivska str., 6th floor, 04107, Kyiv, Ukraine
info@uarep.com | Toll-free tel: 0-800-215232

Date of the latest revision of the instructions for use:
DD.MM.YYY