

TVEL

DECLARATION OF EC CONFORMITY

WE:

Name of Manufacturer:

Limited Liability Company TVEL

UKRAINE, 36014 Poltava, Petra Doroshenka str. 57

EU Representative:

PRZEDSIĘBIORSTWO Innowacyjno- Handlowe VARIA Ltd.

POLAND, 60-473 Poznan, Biecka str. 10

SRN (Single Registration Number):

Name of product: **Electroconductive gel for ECG, EEG, EMG**

Basic UDI-DI: 482025532ECGEEGGELT9

Product size: From 20 g to 5000 g

Product list: see Annex I

Trade name: ZERO GEL

Risk class:

(per rule 1, chapter III, Annex VIII, regulations MDR 2017/745):

Class "I"

Applied harmonized standards: EN ISO13485:2016

We herewith declare that the mentioned products confirm with the Regulation of the EU MDR 2017/745 for medical devices.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of: TVEL Ltd



Viktor Topolia
Mr. Viktor Topolia

Director

Poltava, 24-05-2021



ANNEX I to the Declaration of Conformity

ZERO GEL electroconductive gel for ECG/EEG/EMG 20 g
ZERO GEL electroconductive gel for ECG/EEG/EMG 40 g
ZERO GEL electroconductive gel for ECG/EEG/EMG 250 g
ZERO GEL electroconductive gel for ECG/EEG/EMG 260 g
ZERO GEL electroconductive gel for ECG/EEG/EMG 500 g
ZERO GEL electroconductive gel for ECG/EEG/EMG 1000 g
ZERO GEL electroconductive gel for ECG/EEG/EMG 5000 g canister
ZERO GEL electroconductive gel for ECG/EEG/EMG 5000 g ekobag maxi pack
ZERO GEL electroconductive gel for ECG/EEG/EMG 5000 g ekobag mini pack
ZERO GEL electroconductive gel for ECG/EEG/EMG 5000 g ekobag single pack
ZERO GEL electroconductive gel for ECG/EEG/EMG 5000 g ekotainer standard pack
ZERO GEL electroconductive gel for ECG/EEG/EMG 5000 g ekotainer maxi pack
ZERO GEL electroconductive gel for ECG/EEG/EMG 5000 g ekotainer single pack

