DECLARATION OF CONFORMITY

We

OHK medical Devices Ltd,
Division of Oneg HaKarmel Ltd.
4th Etgar Str.
Tirat Carmel, 3903215 Israel

declare on our own responsibility that the medical devices:

HemaShock®
Emergency Auto-Transfusion Tourniquet

meets applicable requirements of the Conformity Assessment according to Annex XI; Part A Production Quality Assurance of the Medical Device Regulation (EU) 2017/745.

Classification	Class I respectively based on Rule 4 of the Medical Device Regulation (EU) 2017/745
Applied standards	For the list of the applicable standards and other normative Documents, please refer to the Technical File.
Conformity assessment procedures	Annex XI; Part A
Representative in EU	MedNet EC-REP. Local Reg. No. HRB 17791 Borkstrasse 10, 48163 Munster, Germany

Place	Oneg HaKarmel Ltd
Date	March 17, 2022
Name	Igor Naroditsky
Title	Regulatory Affairs, VP

Signature Igor Naroditsky

Standards and CS	Description
ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN 1041:2008 + A1:2013	Information supplied by the manufacturer with medical devices
EN 15223-1:2016	Symbols to be used with medical device labels, labeling and information to be supplied
IEC 62366-1:2015/AMD 1:2020	Medical devices - Application of usability engineering to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

Model references and part numbers

Product	Basic UDI
HemaShock® Emergency Auto-Transfusion Tourniquet	729001268