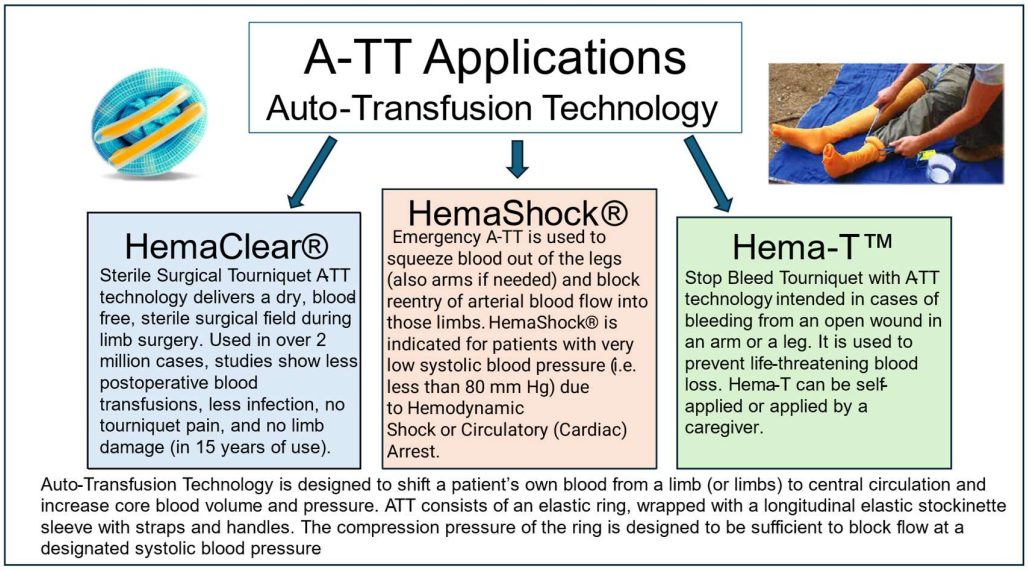
OHK Medical Devices | Division of Oneg HaKarmel Ltd.

January 1, 2026

Declaration

To Whom It May Concern,

OHK Medical Devices, distributes three medical devices, based on OHK's "auto-transfusion" tourniquet technology.



We hereby declare that the Hema-T™, HemaClear® surgical exsanguination tourniquet, and HemaShock© Medical Apparatus for Emergency Medicine (formally A-TT) are legally marketed, Class I, 510(k) exempt devices, registered with the Food and Drug Administration (FDA) as follows.

Proprietary Name(s): Tourniquet, Nonpneumatic. Hema-T Tourniquet. HemaClear Sterile Surgical Tourniquet. HemaShock, Medical Apparatus for use in Emergency Medicine Procedures.
Device Listing Numbers: D338619, D040864
Classification Name: TOURNIQUET, NONPNEUMATIC
Product Code: GAX
Device Class: 1, (510(k)-exempt)
Regulation Number: 878.5900
Medical Specialty: General & Plastic Surgery
Registered Establishment Name: OHK MEDICAL DEVICES Inc
Registered Establishment Number: 3008062566
Owner/Operator: OHK Medical Devices Ltd
Owner/Operator Number: 10024620
Establishment Operations: Manufacturer

View our product status in the FDA database at:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=624908&lpcd=GAX

Best regards,

Larry Murdock, RRT
US Territory Manager
OHK Medical Devices, Inc.
Larry@hemaclear.com
Cell: 951-255-9297 (pacific time)