HemaClear™

Jan 01, 2019

Declaration

To Whom It May Concern,

We hereby declare that the HemaClear® products are listed by the FDA, **listing number D040864**.

Proprietary Name:	HemaClear
Classification Name:	TOURNIQUET, NONPNEUMATIC
Product Code:	GAX
Device Class:	1
Regulation Number:	878.5900
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	OHK MEDICAL DEVICES LTD
Registered Establishment Number:	3003889520
Owner/Operator:	OHK Medical Devices Ltd
Owner/Operator Number:	10024620
Establishment Operations:	Manufacturer

The HemaClear™ product family contains the product models as described below –

Product Number	Product Name
PRH-028-PI-01	HemaClear®/28 (Small) - Pink
PRH-035-FA-01	HemaClear® Model F (Forearm)
PRH-040-GR-01	HemaClear®/40 (Medium)- Green
PRH-040-RE-01	HemaClear®/40 (Medium)- Red
PRH-040-YE-01	HemaClear®/40 (Medium)- Yellow
PRH-060-BL-01	HemaClear®/60 (Large)- Blue
PRH-060-OR-01	HemaClear®/60 (Large)- Orange
PRH-060-BR-01	HemaClear®/60 (Large)- Brown
PRH-090-BW-01	HemaClear®/90 (X-Large)- B&W
PRH-032-MA-01A	HemaClear Model A – Foot & Ankle

Igor Naroditsky

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VP QA/RA
OHK Medical Devices

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Establishment Registration:

Establishment:
OHK MEDICAL DEVICES LTD
Business Trade Names:
(1) EED (2) HemaClear (3) Oneg HaKarmel (4) S-MART

4 Etgar Street
Tirat Carmel Ha Zafon, ISRAEL 3903215
Registration Number: 3003889520
FEI Number*: 3003889520
Status: Active
Date Of Registration Status: 2018

Owner/Operator:
OHK Medical Devices Ltd
2885 Sanford Ave
Sw 14751
Grandville, MI 49418
Owner/Operator Number: 10024620

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Listing Details

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Proprietary Name:	DCB- Desanguinator Compression Band; EED; HemaClear; MBV - Extremity Exsanguination Device; S-MART
Classification Name:	TOURNIQUET, NONPNEUMATIC
Product Code:	GAX
Device Class:	1
Regulation Number:	878.5900
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