



BioDerm, Inc.

EU Declaration of Conformity for BioDerm, Inc. CathGrip Products

Version	Compiled By	Date (MM/DD/YYYY)
1.0	Julie Metzler	01/23/2019
1.1	Julie Metzler	07/22/2019

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the European Parliament and Council Regulation provisions that apply to them and the CE Mark may be affixed.

General Product Name:	CathGrip Product Family
Legal Manufacturer: (Name on Label)	BioDerm, Inc 12320 73 rd Court North Largo, Florida 33773, United States of America
Variants:	As per ANNEX –Product Listing on next page
Intended Use:	Medical tubing and catheter tubing securement device.
MDD Directive Classification:	Class I
Notified Body:	Not Applicable for Class I
Applicable Standards	ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223-1:2016
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Signed for BioDerm Inc.:

Name: Julie Metzler

Position: Specialist, Regulatory Affairs/Quality Assurance

Date: 7-22-19



LYNNETTE BATES
Commission # FF 963860
My Commission Expires
March 09, 2020

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacture's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

L. Bates
7/22/19





Declaration of Conformity for CathGrip Products

ANNEX – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code or UMDNS Code
51250NS	CathGrip Single Strap, Small, Non-Sterile	56631
51350NS	CathGrip Single Strap, Large, Non-Sterile	56631
51301NS	CathGrip Double Strap, Medium, Non-Sterile	56631
51300NS	CathGrip Double Strap, Large, Non-Sterile	56631
54002NS	CathGrip Oval, Small, Non-Sterile	56631
53002NS	CathGrip Oval, Medium, Non-Sterile	56631
54003NS	CathGrip, Large, Non-Sterile	56631
51400NSNW	CathGrip Double Strap, Large, Non-Sterile, No Wipes	56631

ANNEX – Document History

Version	Compiled By	Date (MM/DD/YYYY)	Description
1.0	Julie Metzler	01/23/2019	DOC per product family
1.1	Julie Metzler	07/22/2019	Update GMDN code

