FACET TECHNOLOGIES®

Declaration of Conformity

Manufacturers Name:	Facet Technologies, LLC
Manufacturer's Address:	3900 North Commerce Drive Atlanta, GA USA 30344
European Authorized Representative:	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands +31.70.345.8570 EmergoEurope@ul.com
Name of Device:	FreeStyle Lancets
Device Catalog Numbers:	See Attached
Classification:	Class IIa (MDD Annex IX, Rule 6)
Conformity Route	MDD Annex II (excluding section 4)
Notified Body:	SGS Belgium N.V., CE 1639 Noorderlaan 87 BE-2030 Antwerpen, Belgium
EC Certificate No:	US19/819943525
Valid From:	16 December, 2019

Statement of Conformity:
This EU declaration of conformity is issued under the sole responsibility of Facet Technologies, LLC, the legal manufacturer. Facet declares that the product specified conforms to Annex II of Council Directive 93/42/EEC, as amended, concerning medical devices and Directive 93/42/EEC as transposed in the national laws of the Member States. The single use lancet is considered a Class IIa device as determined by Annex IX, Rule 6 for surgically invasive devices for transient use.

James Bonds

James Bonds
Director, Regulatory Affairs *for Facet Technologies, LLC. Atlanta, Georgia USA*

15 March 2021

Date

CORPORATE HEADQUARTERS
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Attachment to FreeStyle/Thin Lancet Declaration of Conformity

Product Codes	*Product Description*
70853-70	50 Count Sterile Lancets
80119-70	50 Count Sterile Lancets
80118-70	200 Count Sterile Lancets
70849-70	200 Count Sterile Lancets
70848-71	50 Count Sterile Lancets
70848-70	50 Count Sterile Lancets
70849-71	200 Count Sterile Lancets
80119-71	50 Count Sterile Lancets
70854-70	200 Count Sterile Lancets
PRT10377-111	10 Count Sterile Lancets