Asahi Polyslider

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
OneTouch Delica Plus Lancet	mi-Lancet 30G / 114301-592 mi-Lancet 33G / 114302-592

MANUFACTURER		
Name of company	**Address**	**Representative**
ASAHI POLYSLIDER COMPANY, LIMITED	860-2 Misaki, Maniwa, Okayama 719-3226 Japan	Ayumi Yamada

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
LifeScan Deutschland GmbH	Niederkasseler Lohweg 18 40547 Duesseldorf, Germany	Phone: +49 (0) 173 9885164 njanssen@lifescan.com

REGISTRATION INFORMATION	
Notified Body and ID #	**CE certificate number**
SGS Belgium NV ID #: 1639 SGS House, Noorderlaan 87, 2030 Antwerp, Belgium	certificate JP19/040506

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class IIa Rule 6	Annex Ⅱ (excluding section4) of MDD 93/42/EEC Council Directive	See Technical File TF-002

ASAHI POLYSLIDER COMPANY, LIMITED declares that the above products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Tetsuya Ota

TITLE: President **SIGNATURE:** 

DATE: May 13, 2021