Pottery Road,
Dun Laoghaire,
Co. Dublin,
Ireland.
t: +353.1.202.5222
f: +353.1.285.4332

bd.com

DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton, Dickinson and Company Limited, Pottery Road, Dun Laoghaire, Co. Dublin, Ireland.
Authorised Representative:	NA
Manufacturing Site:	Manufactured on behalf of Becton, Dickinson and Company, Limited by: HTL Strefa S.A. ul.Adamowek 7, 95-035 Ozorkow, Poland
Products:	366592 BD Microtainer® Contact-Activated Lancet 1.5 mm x 30G (0.31 mm) 200 Pack 366593 BD Microtainer® Contact-Activated Lancet 1.8 mm x 21G (0.81mm) 200 Pack 366594 BD Microtainer® Contact-Activated Lancet 2.0 mm x1.5 mm 200 Pack 366599 BD Microtainer® Contact-Activated Lancet 2.0 mm x1.5 mm 100 Pack
Classification:	Class IIa, Rule 6
Conformity Assessment Route:	Annex VII and Annex V
GMDN:	61578

We herewith declare that for the above mentioned products, their product design meets the provisions of the European Medical Device Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained at the premises of the manufacturer or subcontractor.

Harmonized standards:	EN 556-1:2001/AC:2006, EN 1041:2008/A1:2013, EN IS0 10993-1:2009/AC:2010, EN IS0 10993-4:2009, EN IS0 10993-5:2009, EN IS0 10993-11:2009, EN ISO 11137-1: 2006/AI: 2015; EN ISO 11137-2:2015; EN ISO 11737-1:2006/AC:2009, EN ISO 11737-2:2009,EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 13485:2012, ISO13485:2003, EN 14155:2011, EN ISO 14971:2012, EN ISO 15223-1: 2016, EN ISO 23908:2013, EN ISO 62366-1
Notified Body:	NSAI 1 Swift Square, Northwood, Santry Dublin 9, Ireland Telephone: 353-1-807-3800 Number of Notified Body: 0050
CE Certificate number:	252.910
Date of issue of original CE certificate:	April, 2013

Date: 01 MAY 2018

Name Andrew Roche
Function QA/RA
Business Unit Becton, Dickinson and Company Limited

Date: 01 MAY 2018

Cormac Reynolds
Director
Becton, Dickinson and Company Limited