kuraray Noritake

Addendum to the original Declaration of Conformity

Name of device: K-ETCHANT GEL

Per 01 November 2021, the EU Authorized Representative as listed on the original DoC has changed.

OLD AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Kuraray Europe GmbH	Philipp-Reis-Str.4, 65795 Hattersheim am Main, Germany	+49.(0)69.305.35835 – phone

NEW AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

DATE: 01/11/2021

UK Type has been unified to EU Type.

OLD ATTACHMENT	
Type	**Product name**
# 013 EU	K-ETCHANT GEL
Type	**Product name**
# 013 UK	K-ETCHANT GEL

NEW ATTACHMENT	
Type	**Product name**
#013-EU	K-ETCHANT GEL

DATE: 01/11/2022

Per 31 January 2023, the address of our EU Authorized Representative as listed on the original DoC has changed.

OLD ADDRESS AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

NEW ADDRESS AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem, The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

DATE: 31/01/2023

Addition/update of standard

OLD APPLIED STANDARDS
EN 1641:2009, EN 1041:2008, ISO 780:2015, ISO 7405:2018, EN ISO 14971:2012, EN ISO 10993-1:2009, ISO 10993-1:2018, ISO 8601-1 :2019, ISO 8601-2:2019, ISO 15223-1 :2016, EN 62366:2008, IEC 62366-1:2015, EN ISO 13485:2016/AC:2016

NEW APPLIED STANDARDS
EN 1641: 2009, EN ISO 20417: 2021, ISO 780: 2015, ISO 7405: 2018 EN ISO 14971: 2019, EN ISO 10993-1: 2020, ISO 10993-1: 2018 ISO 8601-1: 2019, ISO 8601-2: 2019, EN ISO 15223-1: 2021 EN 62366-1: 2015+AC: 2016, IEC 62366-1: 2015+A1: 2020, EN ISO 13485: 2016+AC: 2018

DATE: 01/03/2024

COMPANY REPRESENTATIVE: Satoshi Yamaguchi

TITLE: President **SIGNATURE:** 山口 里志

DATE: 15/03/2024