kuraray Noritake

Addendum to the original Declaration of Conformity

Name of device: CLEARFIL MAJESTY ES Flow

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**
#3301-EU	CLEARFIL MAJESTY ES Flow Low (A1)
#3302-EU	CLEARFIL MAJESTY ES Flow Low (A2)
#3303-EU	CLEARFIL MAJESTY ES Flow Low (A3)
#3304-EU	CLEARFIL MAJESTY ES Flow Low (A3.5)
#3305-EU	CLEARFIL MAJESTY ES Flow Low (A4)
#3306-EU	CLEARFIL MAJESTY ES Flow Low (KA6)
#3307-EU	CLEARFIL MAJESTY ES Flow Low (B1)
#3308-EU	CLEARFIL MAJESTY ES Flow Low (B2)
#3309-EU	CLEARFIL MAJESTY ES Flow Low (XW)
#3310-EU	CLEARFIL MAJESTY ES Flow Low (A2D)
#3311-EU	CLEARFIL MAJESTY ES Flow Low (A3D)
#3312-EU	CLEARFIL MAJESTY ES Flow Low (W)
#3317-EU	CLEARFIL MAJESTY ES Flow Low (A2) TRIAL
#3331-EU	CLEARFIL MAJESTY ES Flow Needle tip (N)
#3321-EU	CLEARFIL MAJESTY ES Flow High (A1)
#3322-EU	CLEARFIL MAJESTY ES Flow High (A2)
#3323-EU	CLEARFIL MAJESTY ES Flow High (A3)
#3324-EU	CLEARFIL MAJESTY ES Flow High (A2D)
#3325-EU	CLEARFIL MAJESTY ES Flow High (A3D)
#3341-EU	CLEARFIL MAJESTY ES Flow Super Low (A1)

#3342-EU	CLEARFIL MAJESTY ES Flow Super Low (A2)
#3343-EU	CLEARFIL MAJESTY ES Flow Super Low (A3)
#3344-EU	CLEARFIL MAJESTY ES Flow Super Low (A3.5)
Type	**Product name**
#3301-UK	CLEARFIL MAJESTY ES Flow Low (A1)
#3302-UK	CLEARFIL MAJESTY ES Flow Low (A2)
#3303-UK	CLEARFIL MAJESTY ES Flow Low (A3)
#3304-UK	CLEARFIL MAJESTY ES Flow Low (A3.5)
#3305-UK	CLEARFIL MAJESTY ES Flow Low (A4)
#3306-UK	CLEARFIL MAJESTY ES Flow Low (KA6)
#3307-UK	CLEARFIL MAJESTY ES Flow Low (B1)
#3308-UK	CLEARFIL MAJESTY ES Flow Low (B2)
#3309-UK	CLEARFIL MAJESTY ES Flow Low (XW)
#3310-UK	CLEARFIL MAJESTY ES Flow Low (A2D)
#3311-UK	CLEARFIL MAJESTY ES Flow Low (A3D)
#3312-UK	CLEARFIL MAJESTY ES Flow Low (W)
#3317-UK	CLEARFIL MAJESTY ES Flow Low (A2) TRIAL
#3331-UK	CLEARFIL MAJESTY ES Flow Needle tip (N)
#3321-UK	CLEARFIL MAJESTY ES Flow High (A1)
#3322-UK	CLEARFIL MAJESTY ES Flow High (A2)
#3323-UK	CLEARFIL MAJESTY ES Flow High (A3)
#3324-UK	CLEARFIL MAJESTY ES Flow High (A2D)
#3325-UK	CLEARFIL MAJESTY ES Flow High (A3D)
#3341-UK	CLEARFIL MAJESTY ES Flow Super Low (A1)
#3342-UK	CLEARFIL MAJESTY ES Flow Super Low (A2)
#3343-UK	CLEARFIL MAJESTY ES Flow Super Low (A3)
#3344-UK	CLEARFIL MAJESTY ES Flow Super Low (A3.5)

NEW ATTACHMENT	
Type	**Product name**
#3301-EU	CLEARFIL MAJESTY ES Flow Low (A1)
#3302-EU	CLEARFIL MAJESTY ES Flow Low (A2)
#3303-EU	CLEARFIL MAJESTY ES Flow Low (A3)
#3304-EU	CLEARFIL MAJESTY ES Flow Low (A3.5)
#3305-EU	CLEARFIL MAJESTY ES Flow Low (A4)
#3306-EU	CLEARFIL MAJESTY ES Flow Low (KA6)
#3307-EU	CLEARFIL MAJESTY ES Flow Low (B1)
#3308-EU	CLEARFIL MAJESTY ES Flow Low (B2)
#3309-EU	CLEARFIL MAJESTY ES Flow Low (XW)
#3310-EU	CLEARFIL MAJESTY ES Flow Low (A2D)
#3311-EU	CLEARFIL MAJESTY ES Flow Low (A3D)
#3312-EU	CLEARFIL MAJESTY ES Flow Low (W)
#3317-EU	CLEARFIL MAJESTY ES Flow Low (A2) TRIAL
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#3321-EU	CLEARFIL MAJESTY ES Flow High (A1)
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#3323-EU	CLEARFIL MAJESTY ES Flow High (A3)
#3324-EU	CLEARFIL MAJESTY ES Flow High (A2D)

#3325-EU	CLEARFIL MAJESTY ES Flow High (A3D)
#3341-EU	CLEARFIL MAJESTY ES Flow Super Low (A1)
#3342-EU	CLEARFIL MAJESTY ES Flow Super Low (A2)
#3343-EU	CLEARFIL MAJESTY ES Flow Super Low (A3)
#3344-EU	CLEARFIL MAJESTY ES Flow Super Low (A3.5)

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, ISO 4049:2009, 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, ISO 4049:2019, EN 62366-1: 2015+AC: 2016, IEC 62366-1: 2015+A1: 2020, EN ISO 13485: 2016+AC: 2018

DATE: 01/02/2024

COMPANY REPRESENTATIVE: Satoshi Yamaguchi

TITLE: President **SIGNATURE:** 山口 聡史

DATE: 28/03/2024