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EC DECLARATION OF CONFORMITY

MANUFACTURER

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AUTHORIZED REPRESENTATIVE

Kowa Pharmaceutical Europe Co. Ltd.
105 Wharfedale Road, Winnersh Triangle, Wokingham, Berkshire, RG41 5RB , U.K.

MEDICAL DEVICE

Common Name: Posterior-chamber intraocular lens, pseudophakic (GMDN=35658)
Product Name: AvanseePreset PN6A
Serial Number: Date of CE marking first applied is 2015/03/02. This Declaration of conformity is valid in connection with the release document for the respective serial number of produced devices.

Applicable standards:

EN ISO13485:2012/ EN ISO14971:2012/ EN62366:2008/ EN1041:2008/
EN ISO11607-1:2009/ EN ISO11607-2:2006/ EN980:2008/
EN 556-1:2001+AC:2006/ EN 556-1:2001+AC:2006/ EN 556-2:2003/
ISO1135-4:2004/ EN ISO11135-1:2007/ ISO 11138-1:2006/
EN ISO 11138-2:2009/ ISO11737-1:2006 +AC:2009/ ISO11979-1:2012/
ISO11979-2:1999+Cor1:2003/ ISO11979-3:2012/ ISO11979-4:2008+Amd1:2012/
ISO11979-5:2006/ ISO11979-6:2007/ ISO11979-7:2014/ EN ISO11979-8:2009/
EN ISO10993-1:2009+AC:2010/ EN ISO10993-3:2009/ EN ISO10993-5:2009/
EN ISO10993-6:2009/ EN ISO10993-7:2008+AC:2009/ ISO10993-10:2010/
EN ISO10993-11:2009/ EN ISO10993-12:2012/ EN ISO10993-18:2009/
ISO 1135-4:2004

DEVICE CLASSIFICATION

Class Ⅱb, Rule8 first paragraph Annex Ⅸ, Medical Device Directive 93/42/EEC

CONFORMITY ASSESSMENT ROUTE

Annex Ⅱ , Medical Device Directive 93/42/EEC

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed in Annex I of EC Directive 93/42/EEC.

Tokyo , 4. Mar. 2015
Place and date of issue

Toshio Inagi
Director of Pharmaceutical Research Department

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Kowa Pharmaceutical Europe Co. Ltd.
105 Wharfedale Road, Winnersh Triangle, Wokingham, Berkshire, RG41 5RB , U.K.

MEDICAL DEVICE

Common Name: Posterior-chamber intraocular lens, pseudophakic (GMDN=35658)
Product Name: AvanseePresetUV PU6A
Serial Number: Date of CE marking first applied is 2015/03/04. This Declaration of conformity is valid in connection with the release document for the respective serial number of produced devices.

Applicable standards:

EN ISO13485:2012/ EN ISO14971:2012/ EN62366:2008/ EN1041:2008/
EN ISO11607-1:2009/ EN ISO11607-2:2006/ EN980:2008/
EN 556-1:2001+AC:2006/ EN 556-1:2001+AC:2006/ EN 556-2:2003/
ISO1135-4:2004/ EN ISO11135-1:2007/ ISO 11138-1:2006/
EN ISO 11138-2:2009/ ISO11737-1:2006 +AC:2009/ ISO11979-1:2012/
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ISO 1135-4:2004

DEVICE CLASSIFICATION

Class Ⅱb, Rule8 first paragraph Annex Ⅸ, Medical Device Directive 93/42/EEC

CONFORMITY ASSESSMENT ROUTE

Annex Ⅱ , Medical Device Directive 93/42/EEC

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed in Annex I of EC Directive 93/42/EEC.

Tokyo , 4. Mar. 2014
Place and date of issue

Toshio Inagi
Director of Pharmaceutical Research Department