

CONTENTS

1. PREAMBLE – INTENDED USE..... 3

2. MANUFACTURER DATA & SRN 4

3. MEDICAL DEVICE..... 4

4. MD NOMENCLATURE 6

5. CONFORMITY ASSESSMENT 7

6. NOTIFY BODY & CERTIFICATIONS 8

7. Anexo A – MODELOS Lentes de Contacto Blandas Estériles / MODELS - Sterile Soft Contact Lenses 9

7.1. TF-01 Products of Methafilcon 9

7.2. TF-02 Products of Silicone lathed11

7.3. TF-03 Products of Vistaflex GL13

7.4. TF-04 Products of GMA & 2-HEMA.....14

8. Anexo B – MARCAS PRIVADAS /PRIVATE BRANDS 15

9. Anexo C: Clasificación de los materiales utilizados para fabricar las lentes / Classification of lens material used 16

10. Anexo D: Authorised Representative in Third countries 17

10.1. Switzerland17

10.2. United Kingdom17

| | |
|---------------------------|----|
| 11. CHANGES CONTROL | 18 |
| 12. APPROVAL | 19 |

| | | |
|---|--|-----------------------------------|
|  | DECLARACIÓN CE DE CONFORMIDAD EC CONFORMITY DECLARATION | DoC CE SP-01 Versión 11 |
| | | Página / Page 3 / 20 |

1. PREAMBLE – INTENDED USE

Esta declaración de conformidad se publica bajo la única responsabilidad del fabricante.
mark'ennovy Personalized Care S.L. fabrica un único tipo producto sanitario (lentes de contacto clase IIa).

El uso previsto de las lentes de contacto correctivas de mark'ennovy incluidas en esta declaración, es corregir los defectos refractivos que ocurren naturalmente (por ejemplo, miopía, hipermetropía, astigmatismo, presbicia) con el propósito de mejorar las condiciones de visión.

Tanto la miopía como la hipermetropía pueden incluir variaciones astigmáticas o de presbicia.

La adaptación de las lentes de contacto debe ser realizado por un profesional cualificado (oftalmólogo, optometrista u óptico) y el usuario debe tener ojos sanos.

Manejo de la miopía: además, las lentes de contacto MYLO pueden reducir la tasa de progresión de la miopía.

This declaration of conformity is issued under the sole responsibility of the manufacturer.
mark'ennovy Personalized Care S.L. manufactures contact lenses class IIa.

The intended use of mark'ennovy contact lenses, included at this declaration, is to correct refractive vision conditions that occur naturally (e.g., myopia, hyperopia, astigmatism, presbyopia).

Myopia also called short sightedness and Hyperopia also called Hypermetropia or long sightedness.

Both may include astigmatic or presbyopia variations.

The fitting of contact lenses must be done by a qualified optical practitioner (Ophthalmologist, Optometrist or Optician) and the user needs to have healthy eyes.

Myopia Management: additionally, MYLO contact lenses may reduce the rate of myopia progression.

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| | | <p>Página / Page 4 / 20</p> |

2. MANUFACTURER DATA & SRN

| | |
|---|---|
| FABRICANTE MANUFACTURER | mark'ennovy Personalized Care S.L |
| DIRECCIÓN ADDRESS | Ronda del Carralero 25 Poligono Industrial El Carralero, 28222 Majadahonda, Madrid Spain |
| SRN - EUDAMED Single Registration Number | Manufacturer: ES-MF000001436 Importer: ES-IM000001440 |

3. MEDICAL DEVICE


| | |
|--|---|
| PRODUCTO PRODUCT | <p>mark'ennovy diseña, desarrolla, fabrica, distribuye y comercializa el tipo de producto sanitario: LENTES DE CONTACTO CORRECTIVAS de hidrogel de silicona fabricadas mediante torneado. La finalidad prevista de estos productos es la compensación óptica o corrección de errores refractivos. Adicionalmente, Mylo puede reducir la tasa de progresión de la miopía</p> <p>mark'ennovy design, develops, manufactures, distributes and sales the type of Medical Devices: CORRECTIVE CONTACT LENSES, daily wear of silicone hydrogel manufactured by lathing process. The intended use of these products it is the optical compensation or correction of refractive errors. additionally, MYLO contact lenses may reduce the rate of myopia progression</p> |
| CODING OF THE DEVICE ACCORDING TO THE EUROPEAN REGULATION 2017/2185 CODES | MDN 1206 Non-active and non-implantable ophthalmologic device MDS 1005 Sterile devices |

| | |
|--------------------------------|---|
| CLASSIFICATION | <p><u>Class IIa medical device, rule 5</u> Short term, non-surgically invasive whose continuous contact with the corneal surface is over 60 minutes but less than 30 days.</p> |
| ADDITIONAL DESCRIPTION | <p>Las lentes de contacto mark'ennovy no contienen ningún derivado de sangre humana, ácido hialurónico (hialuronato, hialuronato de sodio) u otra sustancia de origen animal, microbiano o recombinante. mark'ennovy contact lenses does not contain any human blood derivative, hyaluronic acid (hyaluronate, sodium hyaluronate) or another substance of animal, microbial or recombinant origin</p> <p>Las lentes de contacto mark'ennovy no se han diseñado para administrar fármacos. mark'ennovy contact lenses are not designed to administer medicinal products.</p> <p>Para la fabricación de las lentes no se utilizan materiales de tejido animal. There is no use of tissues of animal origin for manufacturing mark'ennovy contact lenses.</p> <p>Los productos mark'ennovy no contienen ftalatos. mark'ennovy products do not contain phthalates.</p> |
| TECHNICAL DOCUMENTATION | <p>TF-01 Methafilcon contact lenses TF-02 Silicone Hydrogel lathed contact lenses TF-03 Vistaflex Gentle contact lenses TF-04 GMA & 2-HEMA contact lenses List of models at Annex A</p> |

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| | | <p>Página / Page 6 / 20</p> |

4. MD NOMENCLATURE

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|---|---|
| <p>EUROPEAN MD NOMENCLATURE</p> | <p>Q021004102 1 Ophthalmic device, corrective optical device, contact lenses, hydrogel, reusable</p> |
| <p>OTHER INTERNATIONAL MD NOMENCLATURE</p> | <p>GMDN: 47842 lentes de contacto (blandas) correctivas, uso diario (estériles) Son productos sanitarios Clase IIa con regla de clasificación 5.</p> <p>GMDN: 47842 Soft corrective contact lenses, daily wear (Sterile) Medical devices class IIa under classification rule 5.</p> |

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| | | <p>Página / Page 7 / 20</p> |

5. CONFORMITY ASSESSMENT

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| <p>EVALUACIÓN DE CONFORMIDAD CONFORMITY ASSESSMENT</p> | <p>Los modelos se encuentran detallados en los Anexos adjuntos (A y B) y cumplen con los Requisitos Esenciales, especificados en el Anexo I de la Directiva 93/42/CEE y su actualización Directiva 2007/47/CE relativa a los Productos Sanitarios y Real decreto 1591:2009 y cumple con las especificaciones comunes de lentes de contacto descritas en la norma EN ISO 14534:2015 “Requisitos fundamentales”.</p> <p>En el documento STD-00 “List of Standard” ligado al Expediente técnico se encuentran detalladas todas las normas y legislación vigente de aplicación al producto.</p> <p>The models described at the attached Annexes (A and B) are conform with, the Essential Requirements of Annex 1 of Medical Device Directive 93/42/CEE (amended by Directive 2007/47/CE) and comply with common specifications for contact lenses described at EN ISO 14534:2015 “Fundamental requirements”.</p> <p>The document STD-00 “List of Standards” associated to Technical File includes reference to all Standards and Laws that applies to the product.</p> |
| <p>ESTANDARES APLICADOS STANDARDS APPLIED</p> | <p>Nuestro sistema de calidad está basado en la EN ISO 13485:2016/A11:2021 Las lentes de contacto blandas se suministran en estado estéril de acuerdo con las normas EN-556:2002 y EN 17665-1:2007 de esterilización de productos sanitarios mediante calor húmedo.</p> <p>Our Quality Management System is based on EN ISO 13485:2016/A11:2021 Soft Contact lenses are supplied sterile according to the standards EN-556:2002 and EN 17665-1:2007 of sterilization of medical devices by moist heat.</p> |

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| | | <p>Página / Page 8 / 20</p> |

6. NOTIFY BODY & CERTIFICATIONS

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| <p>ORGANISMO NOTIFICADO NOTIFY BODY</p> | <p>SGS BELGIUM NV Notified Body number:1639 (RPR Antwerpen BTW BE 0404.882.750) SGS House - Noorderlaan 87 2030 Antwerpen Belgium</p> |
| <p>CERTIFICADO CE EC CERTIFICATE</p> | <p>ES19/86757</p> <p>Esta declaración tiene su apoyo en el Certificado CE número ES19/86757 issue 1, de Sistema completo de Garantía de Calidad de acuerdo con el Anexo II valido desde el 16 de diciembre de 2019 hasta 24 de mayo de 2024 emitido por el Organismo Notificado SGS BELGIUM NV CE 1639, auditado con periodicidad anual.</p> <p>This Declaration is supported on EC Certificate ES19/86757 issue 1, full Quality Assurance system according to Annex II of the directive 93/42/EEC valid from 16th December 2019 to May 24th, 2024, issued by our Notify Body SGS BELGIUM NV CE 1639 that is audited under yearly periodicity.</p> |
| <p>INICIO DE MARCADO CE START OF CE-MARKING</p> | <p>Certificación CE inicial data del 04-06-1998. Desde el 13 julio 2010, la certificación estuvo bajo SGS UK (0120). Debido al Brexit, desde el 19 de diciembre 2019, la certificación se migró a SGS Bélgica, SGS BE (1639).</p> <p>First CE certification in 04-06-1998. From 13rd July 2010, the EC certification with SGS UK (0120) Since the 16th of December 2019, the EC certification was migrated to the Belgian SGS, SGS BE (1639)</p> |

7. Annex A – MODELOS Lentes de Contacto Blandas Estériles / MODELS - Sterile Soft Contact Lenses

7.1. TF-01 Products of Methafilcon

| NOMBRE COMERCIAL/ BRAND NAME | GEOMETRY | FABRICATION | MATERIAL | HANDLING TINT | FILTER | TYPE OF REPLACEMENT | GMDN | PRODUCT CODE |
|---------------------------------|---------------------|-------------|------------------------------------|------------------|--------|------------------------|-------|-----------------|
| Xtensa Aspheric | Aspheric | moulded | Methafilcon Filcon 4 (19) [55%] | Blue | | Monthly | 47842 | 10001 |
| Xtensa Toric | Toric | moulded | Methafilcon Filcon 4 (19) [55%] | Blue | | Monthly | 47842 | 10002 |
| Xtensa MF | Multifocal | moulded | Methafilcon Filcon 4 (19) [55%] | Blue | | Monthly | 47842 | 10003 |
| Xtensa Rx | Toric | lathed | Methafilcon Filcon 4 (19) [55%] | Blue | | Monthly | 47842 | 10004 |
| Xtensa Rx MFT | Multifocal toric | lathed | Methafilcon Filcon 4 (19) [55%] | Blue | | Monthly | 47842 | 10005 |
| Seven | Aspheric | moulded | Methafilcon Filcon 4 (19) [55%] | Blue | | Weekly | 47842 | 10006 |
| Seven | Toric | moulded | Methafilcon Filcon 4 (19) [55%] | Blue | | Weekly | 47842 | 10007 |
| Seven | Multifocal | moulded | Methafilcon Filcon 4 (19) [55%] | Blue | | Weekly | 47842 | 10008 |



DECLARACIÓN CE DE CONFORMIDAD
EC CONFORMITY DECLARATION

DoC CE **SP-01**
Versión 11

Página / Page
10 / 20

| NOMBRE COMERCIAL/ BRAND NAME | GEOMETRY | FABRICATION | MATERIAL | HANDLING TINT | FILTER | TYPE OF REPLACEMENT | GMDN | PRODUCT CODE |
|---------------------------------|------------------|-------------|------------------------------------|---------------|--------|---------------------|-------|--------------|
| Seven Rx | Toric | lathed | Methafilcon Filcon 4 (19) [55%] | Blue | | Weekly | 47842 | 10013 |
| Seven Rx | Aspheric | lathed | Methafilcon Filcon 4 (19) [55%] | Blue | | Weekly | 47842 | 10014 |
| Seven Rx | Multifocal | lathed | Methafilcon Filcon 4 (19) [55%] | Blue | | Weekly | 47842 | 10015 |
| Seven Rx | multifocal toric | lathed | Methafilcon Filcon 4 (19) [55%] | Blue | | Weekly | 47842 | 10016 |
| IndiGO | Aspheric | moulded | Methafilcon Filcon 4 (18) [52%] | Green | UV | Daily | 47841 | 10017 |
| Xtensa Rx SPH | Aspheric | lathed | Methafilcon Filcon 4 (19) [55%] | Blue | | Monthly | 47842 | 10018 |
| Xtensa Rx MF | Multifocal | lathed | Methafilcon Filcon 4 (19) [55%] | Blue | | Monthly | 47842 | 10019 |

7.2. TF-02 Products of Silicone lathed

| NOMBRE COMERCIAL/ BRAND NAME | GEOMETRY | FABRICATION | MATERIAL | HANDLING TINT | FILTER | TYPE OF REPLACEMENT | GMDN | PRODUCT CODE |
|---------------------------------|---------------------|-------------|----------------------------------|------------------|--------|------------------------|-------|-----------------|
| Saphir Rx SPH | spherical | lathed | Silicone Filcon 5B (60) [75%] | Blue | UV | Monthly | 47842 | 20001 |
| Saphir Rx MF | multifocal | lathed | Silicone Filcon 5B (60) [75%] | Blue | UV | Monthly | 47842 | 20002 |
| Saphir Rx MF Toric | multifocal toric | lathed | Silicone Filcon 5B (60) [75%] | Blue | UV | Monthly | 47842 | 20003 |
| Saphir Rx Toric | toric | lathed | Silicone Filcon 5B (60) [75%] | Blue | UV | Monthly | 47842 | 20004 |
| Saphir SPH | spherical | lathed | Silicone Filcon 5B (60) [75%] | Clear | - | 3-Monthly | 47842 | 20005 |
| Saphir MF | multifocal | lathed | Silicone Filcon 5B (60) [75%] | Clear | - | 3-Monthly | 47842 | 20006 |
| Saphir MF Toric | multifocal toric | lathed | Silicone Filcon 5B (60) [75%] | Clear | - | 3-Monthly | 47842 | 20007 |
| Saphir Toric | toric | lathed | Silicone Filcon 5B (60) [75%] | Clear | - | 3-Monthly | 47842 | 20008 |
| Brilliant Sph | spherical | lathed | Silicone Filcon 5B (60) [75%] | Clear | - | Monthly | 47842 | 20009 |
| Brilliant MF | multifocal | lathed | Silicone Filcon 5B (60) [75%] | Clear | - | Monthly | 47842 | 20010 |
| Brilliant MF Toric | multifocal toric | lathed | Silicone Filcon 5B (60) [75%] | Clear | - | Monthly | 47842 | 20011 |
| Brilliant Toric | toric | lathed | Silicone Filcon 5B (60) [75%] | Clear | - | Monthly | 47842 | 20012 |

| NOMBRE COMERCIAL/ BRAND NAME | GEOMETRY | FABRICATION | MATERIAL | HANDLING TINT | FILTER | TYPE OF REPLACEMENT | GMDN | PRODUCT CODE |
|---------------------------------|------------------|-------------|----------------------------------|---------------|--------|---------------------|-------|--------------|
| MYLO | aspherical | lathed | Silicone Filcon 5B (60) [75%] | Blue | UV | Monthly | 47842 | 20013 |
| EDOF | multifocal | lathed | Silicone Filcon 5B (60) [75%] | Blue | UV | Monthly | 47842 | 20014 |
| Blu:gen SPH | spherical | lathed | Silicone Filcon 5B (60) [75%] | Green | UV | Monthly | 47842 | 20015 |
| Blu:gen Toric | toric | lathed | Silicone Filcon 5B (60) [75%] | Green | UV | Monthly | 47842 | 20016 |
| Blu:gen MF | multifocal | lathed | Silicone Filcon 5B (60) [75%] | Green | UV | Monthly | 47842 | 20017 |
| Blu:gen MF Toric | multifocal toric | lathed | Silicone Filcon 5B (60) [75%] | Green | UV | Monthly | 47842 | 20018 |
| Blu:kidz SPH | spherical | lathed | Silicone Filcon 5B (60) [75%] | Green | UV | Monthly | 47842 | 20019 |
| Blu:kidz Toric | toric | lathed | Silicone Filcon 5B (60) [75%] | Green | UV | Monthly | 47842 | 20020 |
| Blu:kidz MF | multifocal | lathed | Silicone Filcon 5B (60) [75%] | Green | UV | Monthly | 47842 | 20021 |
| Blu:kidz MF Toric | multifocal toric | lathed | Silicone Filcon 5B (60) [75%] | Green | UV | Monthly | 47842 | 20022 |
| Blu:ssentials SPH | spherical | lathed | Silicone Filcon 5B (60) [75%] | Green | UV | Monthly | 47842 | 20023 |
| Blu:ssentials Toric | toric | lathed | Silicone Filcon 5B (60) [75%] | Green | UV | Monthly | 47842 | 20024 |
| Blu:ssentials MF | multifocal | lathed | Silicone Filcon 5B (60) [75%] | Green | UV | Monthly | 47842 | 20025 |
| Blu:ssentials MF Toric | multifocal toric | lathed | Silicone Filcon 5B (60) [75%] | Green | UV | Monthly | 47842 | 20026 |

New House Branding products: [George by mark'ennovy 6pk](#) and [Aera RX by mark'ennovy 3pk](#) (added other brands of Saphir RX).


7.3. TF-03 Products of Vistaflex GL

| NOMBRE COMERCIAL/ BRAND NAME | GEOMETRY | FABRICATION | MATERIAL | HANDLING TINT | FILTER | TYPE OF REPLACEMENT | GMDN | PRODUCT CODE |
|---------------------------------|---------------------|-------------|-------------------------------------|------------------|--------|------------------------|-------|-----------------|
| Gentle 80 SPH | spherical | lathed | Vistaflex GL Filcon 2 (60) [80%] | Blue | UV | Monthly | 47842 | 30001 |
| Gentle 80 Toric | toric | lathed | Vistaflex GL Filcon 2 (60) [80%] | Blue | UV | Monthly | 47842 | 30002 |
| Gentle 80 MF | multifocal | lathed | Vistaflex GL Filcon 2 (60) [80%] | Blue | UV | Monthly | 47842 | 30003 |
| Gentle 80 MFT | multifocal toric | lathed | Vistaflex GL Filcon 2 (60) [80%] | Blue | UV | Monthly | 47842 | 30004 |
| Gentle 59 SPH | spherical | lathed | Vistaflex GL Filcon 2 (30) [59%] | Blue | UV | Monthly | 47842 | 30005 |
| Gentle 59 Toric | toric | lathed | Vistaflex GL Filcon 2 (30) [59%] | Blue | UV | Monthly | 47842 | 30006 |
| Gentle 59 MF | multifocal | lathed | Vistaflex GL Filcon 2 (30) [59%] | Blue | UV | Monthly | 47842 | 30007 |
| Gentle 59 MFT | multifocal toric | lathed | Vistaflex GL Filcon 2 (30) [59%] | Blue | UV | Monthly | 47842 | 30008 |

New House Branding products: [Yvonne by mark'ennovy 6pk](#) (added other brand of Gentle 59).

7.4. TF-04 Products of GMA & 2-HEMA

| NOMBRE COMERCIAL/ BRAND NAME | GEOMETRY | FABRICATION | MATERIAL | HANDLING TINT | FILTER | TYPE OF REPLACEMENT | GMDN | PRODUCT CODE |
|------------------------------------|---------------------|-------------|-------------------------------|---------------|--------|----------------------------|-------|--------------|
| Quattro SPH | spherical | lathed | GMA Filcon 1 (15) [49%] | Blue | UV | Traditional & 3-monthly | 47842 | 40001 |
| Quattro MF | multifocal | lathed | GMA Filcon 1 (15) [49%] | Blue | UV | Traditional & 3-monthly | 47842 | 40002 |
| Quattro TORIC | toric | lathed | GMA Filcon 1 (15) [49%] | Blue | UV | Traditional & 3-monthly | 47842 | 40003 |
| Equilibria SPH | spherical | lathed | GMA Filcon 2 (24) [59%] | Blue | - | 3-monthly | 47842 | 40004 |
| Equilibria MULTIFOCAL | multifocal | lathed | GMA Filcon 2 (24) [59%] | Blue | - | 3-monthly | 47842 | 40005 |
| Equilibria MULTIFOCAL TORIC | multifocal toric | lathed | GMA Filcon 2 (24) [59%] | Blue | - | 3-monthly | 47842 | 40006 |
| Equilibria TORIC | toric | lathed | GMA Filcon 2 (24) [59%] | Blue | - | 3-monthly | 47842 | 40007 |
| SPH5 | spherical | lathed | GMA Filcon 2 (24) [59%] | Blue | - | Traditional | 47842 | 40008 |
| 5T | toric | lathed | GMA Filcon 2 (24) [59%] | Blue | - | Traditional | 47842 | 40009 |
| ES 43 | spherical | lathed | 2-Hema Filcon 1 (10) [38%] | Green | - | Traditional | 47842 | 40010 |
| ET 43 | toric | lathed | 2-Hema Filcon 1 (10) [38%] | Green | - | Traditional | 47842 | 40011 |

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| | | <p>Página / Page 15 / 20</p> |

8. Anexo B – MARCAS PRIVADAS /PRIVATE BRANDS

Declaración de Conformidad para MARCAS PRIVADAS

Existen MARCAS PRIVADAS de lentes mark'ennovy con determinados clientes, en base a acuerdos comerciales. Estas marcas se detallan en el listado de marcas privadas (Documento DC PL) como complemento a esta Declaración de conformidad y donde se detalla la equivalencia de cada marca privada con el producto mark'ennovy.

Todas las lentes se fabrican por mark'ennovy Personalized Care.

Dependiendo de los volúmenes se usa:

- Caja impresa privada o
- Caja blanca con etiqueta comercial privada

Conformity Declaration of PRIVATE BRAND

There are PRIVATE BRANDS of mark'ennovy lenses with nominated clients, based on commercial agreements. These brands are listed in the Conformity Declaration of Private label (Document DC PL), as a complement of this declaration and where it is detailed the private Brand name and the equivalent mark'ennovy product.

All the contact lenses are manufactured by mark'ennovy Personalized Care.

Depending on the volume, we can supply in two versions:

- A specially printed private brand pack/ carton or
- A White box with a private brand over label

9. Annex C: Clasificación de los materiales utilizados para fabricar las lentes / Classification of lens material used

| Type of lens material used | % Water | Classification lens material per ISO 18369-1:2017 |
|--------------------------------------|---------|---|
| Silicone hydrogel 75% (clear) | 75% | Filcon 5B (60) [75%] |
| Silicone hydrogel 75% (green) | 75% | Filcon 5B (60) [75%] |
| Silicone hydrogel 75% (blue) | 75% | Filcon 5B (60) [75%] |
| Vistaflex GL 80% | 80% | Filcon 2 (60) [80%] |
| Vistaflex GL 59% | 59% | Filcon 2 (30) [59%] |
| GMA 59% | 59% | Filcon 2 (24) [59%] |
| GMA 49% | 49% | Filcon 1 (15) [49%] |
| 2-Hema 38% | 38% | Filcon 1 (10) [38%] |
| Methafilcon 55% | 55% | Filcon 4 (19) [55%] |
| Filcon IV 1 52% | 52% | Filcon 4 (18) [52%] |

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| | | <p>Página / Page 17 / 20</p> |


10. Annex D: Authorised Representative in Third countries

10.1. Switzerland

Decomplic AG
Freiburgstrasse 3
CH-3010 Bern

10.2. United Kingdom

Vista Optics Limited:
Gorse Lane,
Widnes WA8 0RP
Cheshire

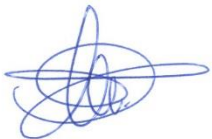

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|---|--|-----------------------------------|
|  | DECLARACIÓN CE DE CONFORMIDAD EC CONFORMITY DECLARATION | DoC CE SP-01 Versión 11 |
| | | Página / Page 18 / 20 |

11. CHANGES CONTROL

| Version | Date | Reason for updating |
|---------|------------|--|
| 9 | 01-04-2021 | <p>Se añade filtro UV y tinte de manipulación a Saphir RX, SRN y MDN 1206 and MDS 1005 (MDR). Actualización formato.</p> <p>Added UV filter and blue handling tint to Saphir Rx, SRN and MDN 1206 and MDS 1005 (MDR). Format upgrade.</p> |
| 10 | 07-01-2022 | <p>Se modifica capítulo de preámbulo y se añade párrafo de “intended use” Se revisa DoC para adaptación a MDR, según Anexo IV y artículo 19 (Pendiente añadir UDI-Básico y cumplimiento con MDR cuando aplique) Se eliminan por descatalogación los modelos de lentes moldeadas de Methafilcon 10009,10010,10011 y 10012 Se añaden los modelos Xtensa RX SPH y Xtensa RX MF, omitidos por error</p> <p>Preamble chapter is amended and "intended use" paragraph is added DoC is revised for adaptation to MDR, according to Annex IV and Article 19 (Outstanding when applicable: to add UDI-Basic and compliance with MDR) Methafilcon molded lens models 10009,10010,10011 and 10012 removed Xtensa RX SPH and Xtensa RX MF models are added, omitted by mistake</p> |
| 11 | 1-03-2022 | <p>New structure to be aligned with new MDR. Added specific titles. Added European MD Nomenclature and 2017/2185 CODES. Added the A11:2021 at EN ISO 13485:2016. Moved content of compliance declaration to additional description within chapter 3. Medical Device Added Authorized Representatives in Third countries. New House Branding products: - George by mark'ennovy 6pk_Saphir RX - Yvonne by mark'ennovy 6pk_Gentle 59 - Aera RX by mark'ennovy 3pk_Saphir RX</p> |

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| | | <p>Página / Page 19 / 20</p> |

12. APPROVAL

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| <p>LUGAR Y FECHA DE EMISIÓN PLACE, DATE OF ISSUE</p> | | <p>Madrid, 1st March 2022</p> |
| <p>FIRMAS SIGNATURES</p> | <p>Directora Garantía de Calidad de Grupo. Técnico Responsable Madrid</p> <p>QARA Group director Mercedes López</p> |  |
| | <p>Representante legal</p> <p>Group C.O.O Stefano Larosa</p> |  |



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EC CONFORMITY DECLARATION

DoC CE **SP-01**
Versión 11

Página / Page
20 / 20