

DoC #: Ofar-0004

Importer:

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verklaart onder eigen verantwoordelijkheid dat de beschreven medische hulpmiddelen (risicoklasse 1) in bijlage 1 conform zijn aan de eisen van de verordening EU 2017/745, bijlage VIII (EG richtlijn over medische hulpmiddelen), waarvan het gebruik bestaat in de correctie van het visuele defect van ouderdomsverziendheid en conform is aan de eisen van de Europese geharmoniseerde norm DIN EN 14139:2010.



erklärt in eigener Verantwortung dass die beschriebene Medizinprodukte (Risikoklasse 1) in Anlage 1 übereinstimmen mit den Bestimmungen der Verordnung EU 2017/745, Anhang VIII (EG-Richtlinie über Medizinprodukte), dessen beabsichtigter Zweck die Korrektur des Sehfehlers der einfachen Altersweitsichtigkeit ist und übereinstimmt mit der einzelstaatlichen Norm, durch die harmonisierte Norm DIN EN 14139:2010.



declares under sole responsibility that the described medical devices (class 1) in attachment 1 are in conformity with the provisions of Council Regulation EU 2017/745, attachment VIII (EC-directive on medical devices) which is intended for correcting the vision problems of simple presbyopia and with the national standard transposing harmonized standards DIN EN 14139:2010.



déclare sous seule responsabilité que les dispositifs médicaux (classe 1) décrit à l'annexe 1 sont conformes aux dispositions de règlement UE 2017/745, addition VIII (directive EC sur les médicaments), conçu pour corriger le défaut visuel de la presbytie simple et à la norme nationale transposant les normes harmonisée DIN EN 14139:2010.

Bijlage 1/ Anlage 1/ Attachment 1/ L'annexe 1

| | | | | | | | |
|------------|-----------|-----------|-----------|----------|----------|-----------|----------|
| CF-001 | LE-0104A | LE-0129I | LE-0137SF | LE-0150H | LE-0163D | LE-0178D | LE-0188B |
| CF-0002A | LE-0109A | LE-0129J | LE-0138A | LE-0150J | LE-0163E | LE-0178SA | LE-0189A |
| CF-0002B | LE-0110A | LE-0129K | LE-0138B | LE-0150K | LE-0163F | LE-0178SB | LE-0189B |
| CF-0002C | LE-0114A | LE-0129L | LE-0138C | LE-0150L | LE-0163G | LE-0178SC | LE-0189C |
| CF-0002D | LE-0114B | LE-0129M | LE-0138D | LE-0150M | LE-0163H | LE-0178SD | LE-0189D |
| CF-0003A | LE-0114C | LE-0129N | LE-0138E | LE-0152A | LE-0164A | LE-0179A | LE-0190A |
| CF-0003B | LE-0115A | LE-0130A | LE-0139A | LE-0152B | LE-0164B | LE-0179B | LE-0190B |
| CF-0003C | LE-0115B | LE-0130B | LE-0139B | LE-0155A | LE-0164C | LE-0179C | LE-0190C |
| CF-0003D | LE-0115C | LE-0130C | LE-0140A | LE-0155B | LE-0164D | LE-0180A | LE-0190D |
| CF-0004A | LE-0116A | LE-0130D | LE-0140B | LE-0155C | LE-0164E | LE-0180B | LE-0191A |
| CF-0004B | LE-0116B | LE-0131A | LE-0141A | LE-0155D | LE-0165A | LE-0180C | LE-0191B |
| CF-0004C | LE-0120A | LE-0131C | LE-0144A | LE-0155E | LE-0165B | LE-0181A | LE-0191C |
| CF-0004D | LE-0120B | LE-0134AA | LE-0145A | LE-0155F | LE-0165C | LE-0181B | LE-0191D |
| LB-0167A | LE-0120C | LE-0134AB | LE-0145B | LE-0156A | LE-0166A | LE-0181C | LE-0192A |
| LB-0177A | LE-0120D | LE-0134AC | LE-0146A | LE-0156B | LE-0166B | LE-0181D | LE-0192B |
| LB-0194A | LE-0121A | LE-0134AD | LE-0146B | LE-0156C | LE-0166C | LE-0181E | LE-0192C |
| LB-0194B | LE-01215B | LE-0134AE | LE-0146C | LE-0156D | LE-0167A | LE-0182A | LE-0192D |
| LB-0194C | LE-0125A | LE-0134BA | LE-0146D | LE-0157A | LE-0167B | LE-0182B | LE-0192E |
| LE-0100B | LE-0125B | LE-0134BB | LE-0146E | LE-0157B | LE-0167C | LE-0182C | LE-0192F |
| LE-0100C | LE-0125C | LE-0134BC | LE-0146F | LE-0157C | LE-0167D | LE-0182D | LE-0193A |
| LE-0100D | LE-0125D | LE-0134BD | LE-0146G | LE-0157D | LE-0167E | LE-0182E | LE-0195A |
| LE-0100F | LE-0126D | LE-0134BE | LE-0146H | LE-0158A | LE-0167F | LE-0182F | LE-0195B |
| LE-0100I | LE-0127A | LE-0135A | LE-0146I | LE-0158B | LE-0168A | LE-0183A | LE-0195C |
| LE-0100M | LE-0127B | LE-0135B | LE-0146J | LE-0158C | LE-0169A | LE-0183B | LE-0195D |
| LE-0100N | LE-0127C | LE-0135C | LE-0146K | LE-0158D | LE-0169B | LE-0183C | LE-0195E |
| LE-0100O | LE-0127D | LE-0135D | LE-0146M | LE-0159A | LE-0169C | LE-0183D | LE-0196A |
| LE-0102A | LE-0128A | LE-0135E | LE-0146N | LE-0159B | LE-0170A | LE-0183E | LE-0196B |
| LE-0102B | LE-0128B | LE-0136A | LE-0146SN | LE-0159C | LE-0171A | LE-0183F | LE-0196C |
| LE-0102C | LE-0128C | LE-0136B | LE-0148A | LE-0159D | LE-0171B | LE-0184A | LE-0196D |
| LE-0103A | LE-0128D | LE-0136C | LE-0148B | LE-0160A | LE-0171C | LE-0184B | LE-0196E |
| LE-0103B | LE-0128E | LE-0137A | LE-0148C | LE-0160B | LE-0173B | LE-0184C | LE-0200A |
| LE-0103C | LE-0128F | LE-0137B | LE-0148D | LE-0161A | LE-0173C | LE-0184D | LE-0200B |
| LE-0103D | LE-0129A | LE-0137C | LE-0148E | LE-0161B | LE-0173D | LE-0184E | LE-0201A |
| LE-0103E | LE-0129B | LE-0137E | LE-0149A | LE-0161C | LE-0176A | LE-0184F | LE-0201B |
| LE-0103F | LE-0129C | LE-0137F | LE-0149B | LE-0162A | LE-0176B | LE-0185A | LE-0202A |
| LE-0103G-S | LE-0129D | LE-0137SA | LE-0149C | LE-0162B | LE-0176C | LE-0185B | LE-0202B |
| LE-0103H-S | LE-0129E | LE-0137SB | LE-0149D | LE-0162C | LE-0176D | LE-0186A | LE-0203A |
| LE-0103I | LE-0129F | LE-0137SC | LE-0150D | LE-0162A | LE-0178A | LE-0186B | LE-0203B |
| LE-0103J | LE-0129G | LE-0137SD | LE-0150E | LE-0163B | LE-0178B | LE-0187A | LE-0203C |
| LE-0103K | LE-0129H | LE-0137SE | LE-0150F | LE-0163C | LE-0178C | LE-0188A | LE-0203D |