

L'AMYAMERICA

EC Declaration of Conformity

According to the European Medical Device Regulation 2017/745

The manufacturer: L'AMY AMERICA
EUDAMED Actor ID/SRN = US-MF-000027647
40 Richard Avenue, 6th floor, Norwalk CT 06854

EU REP: Authorized Representative FR – AR_00021811 DLSIX Consulting
36 rue du collège 39200 Saint-Claude France

Declares under its sole responsibility that the medical devices listed below and on the following pages meet all provisions of the European Medical Device Regulation 2017/745/EEC.

Product Line: New Balance Optical Frames

GMDN CODE: 32816

GS1 Company Prefix	Internal #	GS1 Company Prefix	Modell reference	GMN # (Basic UDI-DI)
730638	NBOPTMETAL	730638	NBOPTMETAL	730638NBOPTMETALE8
730638	NBOPTPLASTIC	730638	NBOPTPLASTIC	730638NBOPTPLASTIC28
730638	NBOPTCOMBO	730638	NBOPTCOMBO	730638NBOPTCOMBOC6

RISK CLASS: I, according Annex VIII Rule I, MDR 2017/745/EEC

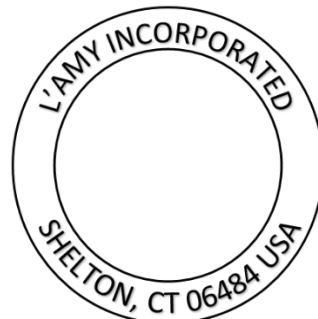
TECHNICAL STANDARD: EN ISO 12878.2018

See Annex I for listing of articles

This Declaration is issued in Norwalk CT USA on 12.17.2024 and expires on 31.12.2025

Marc Gagliano

Marc Gagliano
Vice President of Operations



L'AMYAMERICA

Annex I:

NB400401	NB408701	NB408601	NB413802	NB503803
NB401201	NB408702	NB408602	NB413803	NB503804
NB401302	NB408703	NB408603	NB414001	NB504303
NB401604	NB408704	NB408604	NB414002	NB504803
NB401704	NB408705	NB411401	NB414003	NB504901
NB402501	NB408706	NB411402	NB414101	NB506001
NB403001	NB408901	NB411403	NB414102	NB506003
NB403201	NB408902	NB411501	NB414103	NB506201
NB403203	NB408903	NB411502	NB414201	NB506202
NB403204	NB408904	NB411503	NB414202	NB506203
NB403403	NB409001	NB411701	NB414203	NB506301
NB403404	NB409003	NB411702	NB414301	NB506401
NB404001	NB409004	NB411703	NB414302	NB506402
NB404101	NB409101	NB411802	NB414303	NB506403
NB404103	NB409102	NB411803	NB414503	NB506404
NB404104	NB409103	NB412301	NB414601	NB506701
NB404704	NB409104	NB412302	NB414602	NB507002
NB405204	NB409201	NB412303	NB414702	NB507003
NB405601	NB409202	NB412401	NB414901	NB7011LT02
NB405602	NB409203	NB412402	NB415001	
NB405603	NB409204	NB412403	NB415101	
NB405803	NB409501	NB412502	NB415102	
NB4059X02	NB409503	NB412503	NB415103	
NB407102	NB410001	NB412601	NB415202	
NB407105	NB410002	NB412602	NB415402	
NB407204	NB410003	NB412603	NB415501	
NB407502	NB410102	NB412701	NB415502	
NB407603	NB410103	NB412702	NB415503	
NB407604	NB410201	NB412703	NB415702	
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NB408202	NB411004	NB413501	NB501503	
NB408203	NB411201	NB413502	NB503201	
NB408204	NB411202	NB413701	NB503202	
NB408503	NB411203	NB413801	NB503401	