



# Declaration of Conformity

Teleon Surgical B.V. hereby declares that the products specified below meet the relevant provisions of the European Medical Device Directive 93/42/EEC. This declaration is based on a) on conformity of the production quality assurance system (see below) and b) conformity of said products.

The full quality assurance system is in accordance with the requirements as outlined in Annex II of the Directive, comprising design, manufacture and final inspection. The conformity of the production quality assurance system is outlined in the CE-Certificate as issued by DEKRA Certification B.V., The Netherlands, Notified Body Identification Number 0344. On the certificate reference is made to the type of examination applied.

An application for the said products is not lodged to any other Notified Body than mentioned in this Declaration of Conformity.

This Declaration of Conformity covers the product category *Sterile Intraocular Lenses*, consisting of the following product families:

Product Family	DEKRA Certificate number	Reissued Date	Class	Classification Rule Annex IX MDD
Single Piece Hydrophilic Acrylic Intraocular lenses	2191390CE01	01-03-2020	IIb	8
Single Piece Hydrophobic Acrylic Intraocular lenses	2191390CE01	01-03-2020	IIb	8

On behalf of  
Teleon Surgical B.V.  
Van Rensselaerweg 4 b  
6956AV Spankeren  
The Netherlands

Spankeren, 25-02-2021



M.R.E. Lansu  
CEO



# Annex I – Product List

**Single Piece Hydrophilic Acrylic Intraocular Lenses:**  
 All of the following products are class IIb & UMNDS 16-071

Model	Label REF
QDS-509	PCA81 QDS509
QDS-519	PCX81 QDS519
QDS-519 NY	PCX81 NY QDS519 NY
QDS-519 NYT0	PCX81 NYT0
QDS-519 NYT1	PCX81 NYT1 QDS519 NYT1
QDS-519 NYT2	PCX81 NYT2 QDS519 NYT2
QDS-519 NYT3	PCX81 NYT3 QDS519 NYT3
QDS-519 NYT4	PCX81 NYT4 QDS519 NYT4
QDS-519 NYT5	PCX81 NYT5 QDS519 NYT5
QDS-519 NYT6	PCX81 NYT6 QDS519 NYT6
PCM81 NY	PCM81 NY
PCM81 NYT0	PCM81 NYT0
PCM81 NYT1	PCM81 NYT1
PCM81 NYT2	PCM81 NYT2
PCM81 NYT3	PCM81 NYT3
LU814 VR	LU-814 VR
LU814 T	LU-814 T
LU814MF15	LU-814 MF15
LU814MF20	LU-814 MF20
LU814MF30	LU-814 MF30
LU814MF15T	LU-814 MF15T
LU814MF30T	LU-814 MF30T
L303	L-303
L313	L-313
FB-313	LB-313 FB-313
FB-313 MF15	LB-313 MF15 FB-313 MF15
FB-313 MF15T0	FB-313 MF15T0
FB-313 MF15T1	FB-313 MF15T1
FB-313 MF15T2	FB-313 MF15T2
FB-313 MF15T3	FB-313 MF15T3
FB-313 MF30	FB-313 MF30
FB-313 MF30T0	FB-313 MF30T0
FB-313 MF30T1	FB-313 MF30T1
FB-313 MF30T2	FB-313 MF30T2
FB-313 MF30T3	FB-313 MF30T3
LS313Y	LS-313Y
L323	L-323
LU323	LU-323
L333	L-333
LU313 T	LU-313 T
LU313 TY	LU-313 TY
LS313 T0	LS-313 T0
LS313 T1	LS-313 T1 LS-313 Tx
LS313 T2	LS-313 T2 LS-313 Tx

Model	Label REF
LS313 T3	LS-313 T3 LS-313 Tx
LS313 T4	LS-313 T4 LS-313 Tx
LS313 T5	LS-313 T5 LS-313 Tx
LS313 T6	LS-313 T6 LS-313 Tx
LS313 T7	LS-313 T7 LS-313 Tx
LU323T	LU-323 T
LU323TY	LU-323 TY
LS313 MF15	LS-313 MF15
LS313 MF20	LS-313 MF20
LS313 MF30	LS-313 MF30
LS313 MF80	LS-313 MF80
LU313MF15T	LU-313 MF15T
LU313MF20T	LU-313 MF20T
LU313MF30T	LU-313 MF30T
LU313MF15TY	LU-313 MF15TY
LU313MF20TY	LU-313 MF20TY
LU313MF30TY	LU-313 MF30TY
LS313 MF15T0	LS-313 MF15T0 LS-313 MF15T
LS313 MF15T1	LS-313 MF15T1 LS-313 MF15T
LS313 MF15T2	LS-313 MF15T2 LS-313 MF15T
LS313 MF15T3	LS-313 MF15T3 LS-313 MF15T
LS313 MF15T4	LS-313 MF15T4 LS-313 MF15T
LS313 MF15T5	LS-313 MF15T5 LS-313 MF15T
LS313 MF15T6	LS-313 MF15T6 LS-313 MF15T
LS313 MF15T7	LS-313 MF15T7 LS-313 MF15T
LS313 MF30T0	LS-313 MF30T0
LS313 MF30T1	LS-313 MF30T1 LS-313 MF30T
LS313 MF30T2	LS-313 MF30T2 LS-313 MF30T
LS313 MF30T3	LS-313 MF30T3 LS-313 MF30T
LS313 MF30T4	LS-313 MF30T4 LS-313 MF30T
LS313 MF30T5	LS-313 MF30T5 LS-313 MF30T
LS313 MF30T6	LS-313 MF30T6 LS-313 MF30T
LS313 MF30T7	LS-313 MF30T7 LS-313 MF30T
L302-1v2	L-302-1
L312	L-312
LS312Y	LS-312Y



## Annex I – Product List

**Single Piece Hydrophobic Acrylic Intraocular Lenses:**  
*All of the following products are class IIb & UMNDS 16-071*

<i>Model</i>	<i>Label REF</i>
AN6	AN6
AN6V	AN6V
AN6VM	AN6VM
AN6VT0	AN6VT0
AN6VT1	AN6VT1
AN6VT2	AN6VT2
AN6VT3	AN6VT3