



“QUALITY CLASS LEADING PRODUCTS
HELPING PEOPLE IMPROVE THEIR LIVES“

9Glens® Medical Ltd. • Oberndorferstr. 72 • D-64347 Griesheim

Declaration of Conformity

9Glens® Medical Limited Oberndorferstr. 72 D-64347 Griesheim, Germany	
Product details	
Product Category	Viscoelastica – Shields, Mechanical, Eye, UMDNS code 11-663
Indication of Use	Ophthalmology: adjuvant anterior chamber surgery
Product Names	9G-Gel 2.0%, 9G-Gel 2.4%
Remarks	No animal tissues or derivatives contained
Lot No.	XXX until expiry date of certificate
Classification according to 93/42/EEC:2007-09-05, annex IX	Ila Rule 6
Assessment details	
Notified body	ecm, Bismarckstr. 106, D-52066 Aachen, Germany
Identification number	0481
Route of directive 93/42/EEC:2007-09-05	V and VII
Certificates	Z/18/04204E
Date of issue	29 March 2018
Date of expiry	28 March 2023

We declare under sole responsibility of 9Glens® Medical Limited that the products described above are in compliance with annex I of directive 93/42/EEC amended by 2007/47/EC.

Griesheim, 30 May 2019



9Glens Medical Ltd.
Oberndorfer Str. 72
D- 64347 Griesheim - Germany
Tel: 49- (0) 6155 - 82 58 43
Fax: 49- (0) 6155 - 82 82 89

Karl A. Magill
Managing Director 9Glens® Medical Limited

9Glens® Medical Limited
Oberndorferstr. 72
D-64347 Griesheim / Deutschland
Tel. (49) 06155 – 82 58 43
Fax (49) 06155 – 82 82 89

Geschäftsführer: Karl A. Magill
Amtsgericht Darmstadt HRB 86223
Steuer-Nr.: 007 240 01344
Ust-ID: DE 168145588

Bankverbindung:
Postbank Frankfurt
Konto 44 58 26 08 – BLZ 500 100 60
IBAN DE45 5001 0060 0044 5826 08
SWIFT-/BIC-Code: PBNKDEFF



“QUALITY CLASS LEADING PRODUCTS
HELPING PEOPLE IMPROVE THEIR LIVES“

9Glens® Medical Ltd. • Oberndorferstr. 72 • D-64347 Griesheim

Declaration of Conformity

9Glens® Medical Limited Oberndorferstr. 72 D-64347 Griesheim, Germany	
Product details	
Product Category	Lenses, intraocular UMDNS code 12-324
Indication of Use	Ophthalmology: cataract surgery
Product Names	9G-1CF60, 9G-1CY60, 9G-1ASCX60, 9G-1ASPHO, 9G-1ASPHO-PL
Remarks	n.a.
Serial No.	XXX until expiry date
Classification according to 93/42/EEC, annex IX	IIb Rule 8
Assessment details	
Notified body	ecm, Bismarckstr. 106, D-52066 Aachen, Germany
Identification number	0481
Route of directive 93/42/EEC:2007-09-05	Annex II excl. (4)
Certificates	Z/18/04203E
Date of issue	29 March 2018
Date of expiry	28 March 2023

We declare under sole responsibility of 9Glens® Medical Limited that the products described above are in compliance with the directive 93/42/EEC amended by 2007/47/EC.

Griesheim, 30 May 2019



9Glens Medical Ltd.
Oberndorfer Str. 72
D- 64347 Griesheim - Germany
Tel: 49- (0) 6155 - 82 58 43
Fax: 49- (0) 6155 - 82 82 89

Karl A. Magill
Managing Director 9Glens® Medical Limited

9Glens® Medical Limited
Oberndorferstr. 72
D-64347 Griesheim / Deutschland
Tel. (49) 06155 – 82 58 43
Fax (49) 06155 – 82 82 89

Geschäftsführer: Karl A. Magill
Amtsgericht Darmstadt HRB 86223
Steuer-Nr.: 007 240 01344
Ust-ID: DE 168145588

Bankverbindung:
Postbank Frankfurt
Konto 44 58 26 08 – BLZ 500 100 60
IBAN DE45 5001 0060 0044 5826 08
SWIFT-/BIC-Code: PBNKDEFF



“QUALITY CLASS LEADING PRODUCTS
HELPING PEOPLE IMPROVE THEIR LIVES“

9Glens® Medical Ltd. • Oberndorferstr. 72 • D-64347 Griesheim

Declaration of Conformity

9Glens® Medical Limited Oberndorferstr. 72 D-64347 Griesheim, Germany	
Product details	
Product Category	Capsular Tension Rings (iridocapsular fixation) UMDNS code 16-069
Indication of Use	Ophthalmology: cataract surgery
Product Names	9G-R100, 9G-R110, 9G-R120, 9G-R130, 9G-R140,
Remarks	n.a.
Serial No.	XXX until expiry date
Classification according to 93/42/EEC, annex IX	IIb Rule 8
Assessment details	
Notified body	ecm, Bismarckstr. 106, D-52066 Aachen, Germany
Identification number	0481
Route of directive 93/42/EEC:2007-09-05	Annex II excl. (4)
Certificates	Z/18/04203E
Date of issue	29 March 2018
Date of expiry	28 March 2023

We declare under sole responsibility of 9Glens® Medical Limited that the products described above are in compliance with the directive 93/42/EEC amended by 2007/47/EC.

Griesheim, 30 May 2019



9Glens Medical Ltd.
Oberndorfer Str. 72
D- 64347 Griesheim - Germany
Tel: 49- (0) 6155 - 82 58 43
Fax: 49- (0) 6155 - 82 82 89

Karl A. Magill
Managing Director 9Glens® Medical Limited

9Glens® Medical Limited
Oberndorferstr. 72
D-64347 Griesheim / Deutschland
Tel. (49) 06155 – 82 58 43
Fax (49) 06155 – 82 82 89

Geschäftsführer: Karl A. Magill
Amtsgericht Darmstadt HRB 86223
Steuer-Nr.: 007 240 01344
Ust-ID: DE 168145588

Bankverbindung:
Postbank Frankfurt
Konto 44 58 26 08 – BLZ 500 100 60
IBAN DE45 5001 0060 0044 5826 08
SWIFT-/BIC-Code: PBNKDEFF



“QUALITY CLASS LEADING PRODUCTS
HELPING PEOPLE IMPROVE THEIR LIVES“

9Glens® Medical Ltd. • Oberndorferstr. 72 • D-64347 Griesheim

Declaration of Conformity

9Glens® Medical Limited Oberndorferstr. 72 D-64347 Griesheim, Germany	
Product details	
Product Category	Viscoelastica – Shields, Mechanical, Eye, UMDNS code 11-663
Product Category	Viscoelastica, UMDNS code 11-663
Indication of Use	Ophthalmology: adjuvant anterior chamber surgery
Product Names	9G-Visc 1.0%, 9G-Visc 1.4%, 9G-Visc 1.6%, 9G-Visc 1.8%, 9G-Visc 3.0%,
Remarks	Bacterial fermentation - no animal
Lot No.	XXX until expiry date of certificate
Classification according to 93/42/EEC:2007-09-05, annex IX	Ila Rule 6
Assessment details	
Notified body	ecm, Bismarckstr. 106, D-52066 Aachen, Germany
Identification number	0481
Route of directive 93/42/EEC:2007-09-05	Annex V and VII
Certificate	Z/18/04204E
Date of issue	29 March 2018
Date of expiry	28 March 2023

We declare under sole responsibility of 9Glens® Medical Limited that the products described above are in compliance with annex I of directive 93/42/EEC amended by 2007/47/EC.

Griesheim, 30 May 2019



9Glens Medical Ltd.
Oberndorfer Str. 72
D- 64347 Griesheim - Germany
Tel: 49- (0) 6155 - 82 58 43
Fax: 49- (0) 6155 - 82 82 89

Karl A. Magill
Managing Director 9Glens® Medical Limited

9Glens® Medical Limited
Oberndorferstr. 72
D-64347 Griesheim / Deutschland
Tel. (49) 06155 – 82 58 43
Fax (49) 06155 – 82 82 89

Geschäftsführer: Karl A. Magill
Amtsgericht Darmstadt HRB 86223
Steuer-Nr.: 007 240 01344
Ust-ID: DE 168145588

Bankverbindung:
Postbank Frankfurt
Konto 44 58 26 08 – BLZ 500 100 60
IBAN DE45 5001 0060 0044 5826 08
SWIFT-/BIC-Code: PBNKDEFF



“QUALITY CLASS LEADING PRODUCTS
HELPING PEOPLE IMPROVE THEIR LIVES“

9Glens® Medical Ltd. • Oberndorferstr. 72 • D-64347 Griesheim

Declaration of Conformity

9Glens® Medical Limited Oberndorferstr. 72 D-64347 Griesheim, Germany	
Product details	
Product Category	Lubricating Jellies, UMDNS code 12-401
Indication of Use	Orthopedics, Viscosupplementation
Product Names	9G-Visc intra-articular 1.6% 9G-Visc intra-articular 2.2%
Remarks	Bacterial fermentation – no animal
Lot No.	XXX until expiry date of certificate
Classification according to 93/42/EEC:2007-09-05, annex IX	III Rule 8
Assessment details	
Notified body	ecm, Bismarckstr. 106, D-52066 Aachen, Germany
Identification number	0481
Route of directive 93/42/EEC	II.3 and II.4
Certificates	Z/18/04164E and Z/18/04203E
Date of issue	12. Jan 2018 and 29. March 2018
Date of expiry	14 Dec. 2022 and 28. March 2023

We declare under sole responsibility of 9Glens® Medical Limited that the products described above are in compliance with annex I of directive 93/42/EEC amended by 2007/47/EC.

Griesheim, 30. May 2019



9Glens Medical Ltd.
Oberndorfer Str. 72
D- 64347 Griesheim - Germany
Tel: 49- (0) 6155 - 82 58 43
Fax: 49- (0) 6155 - 82 82 89

Karl A. Magill
Managing Director 9Glens® Medical Limited

9Glens® Medical Limited
Oberndorferstr. 72
D-64347 Griesheim / Deutschland
Tel. (49) 06155 – 82 58 43
Fax (49) 06155 – 82 82 89

Geschäftsführer: Karl A. Magill
Amtsgericht Darmstadt HRB 86223
Steuer-Nr.: 007 240 01344
Ust-ID: DE 168145588

Bankverbindung:
Postbank Frankfurt
Konto 44 58 26 08 – BLZ 500 100 60
IBAN DE45 5001 0060 0044 5826 08
SWIFT-/BIC-Code: PBNKDEFF