

DUPLIKAT



EC Design Examination Certificate
EC Directive 93/42/EEC Annex II, Article 4
Medical Devices

Registration No.: ID 60007598 0001

Report No.: 21111398 004

Manufacturer:

Poly Implant Prothèses
337 Avenue de Bruxelles

83507 La Seyne s/Mer Cedex
France

Manufacturing Facility:

Poly Implant Prothèses
337 Avenue de Bruxelles

83507 La Seyne s/Mer Cedex
France

Product:

Medical Device
Mammary Implants

Identification:

Smooth, micro-textured and textured high cohesivity
gel pre-filled breast implants

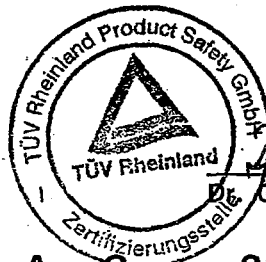
Products: see attachment

The EC design examination certificate refers to the above mentioned product. It certifies that the design documentation of the product complies with Annex II, Article 4 of the directive. The manufacturer is subject to EC surveillance in accordance with Annex II, Article 5 of the directive. The manufacturer is entitled to use this certificate with the manufacturer's declaration of conformity.

Date of Expiry: 14.03.2009

Notified Body

Cologne, 15.03.2004



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

DUPLIKAT



174

Doc. 1/12, Rev. 0

**TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln**

**Attachment to
Registration No.:
Report No.:**

**ID 60007598 0001
21111398 004**

Manufacturer

**Poly Implant Prothèses
337 Avenue de Bruxelles
83507 La Seyne s/Mer Cedex
France**

Scope:

Mammary Implants

IMGHC-LS-S : Smooth surface standard profile high cohesivity gel pre-filled breast implant

CODE	SURFACE	PROFILE	VOLUME (cc)	DIAMETER (mm)	PROJECTION (mm)
IMGHC	SMOOTH	STANDARD	85	87	18
IMGHC	SMOOTH	STANDARD	105	92	20
IMGHC	SMOOTH	STANDARD	125	97	21
IMGHC	SMOOTH	STANDARD	145	102	23
IMGHC	SMOOTH	STANDARD	165	106	26
IMGHC	SMOOTH	STANDARD	185	108	27
IMGHC	SMOOTH	STANDARD	205	110	28
IMGHC	SMOOTH	STANDARD	225	114	29
IMGHC	SMOOTH	STANDARD	245	117	30
IMGHC	SMOOTH	STANDARD	265	124	31
IMGHC	SMOOTH	STANDARD	285	126	32
IMGHC	SMOOTH	STANDARD	305	128	33
IMGHC	SMOOTH	STANDARD	325	130	34
IMGHC	SMOOTH	STANDARD	345	132	35
IMGHC	SMOOTH	STANDARD	365	136	34
IMGHC	SMOOTH	STANDARD	415	141	35
IMGHC	SMOOTH	STANDARD	455	145	36
IMGHC	SMOOTH	STANDARD	505	150	37
IMGHC	SMOOTH	STANDARD	555	156	38
IMGHC	SMOOTH	STANDARD	605	160	39
IMGHC	SMOOTH	STANDARD	655	166	40
IMGHC	SMOOTH	STANDARD		172	41

Cologne, 2004-03-15



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173

Doc. 2/12, Rev. 0

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Product Safety GmbH
Am Grauen Stein, D-51105 Köln**

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**ID 60007598 0001
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Manufacturer

**Poly Implant Prothèses
337 Avenue de Bruxelles
83507 La Seyne s/Mer Cedex
France**

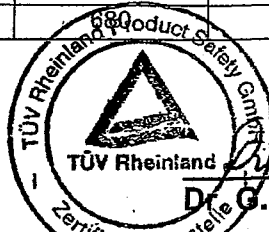
Scope:

Mammary Implants

IMGHC-LS-H : Smooth surface High profile High cohesivity gel pre-filled breast implants

CODE	SURFACE	PROFILE	VOLUME (cc)	DIAMETER (mm)	PROJECTION (mm)
IMGHC	SMOOTH	HIGH	90	80	29
IMGHC	SMOOTH	HIGH	130	84	32
IMGHC	SMOOTH	HIGH	150	90	34
IMGHC	SMOOTH	HIGH	170	94	35
IMGHC	SMOOTH	HIGH	190	98	36
IMGHC	SMOOTH	HIGH	210	102	37
IMGHC	SMOOTH	HIGH	230	105	38
IMGHC	SMOOTH	HIGH	250	109	39
IMGHC	SMOOTH	HIGH	270	112	40
IMGHC	SMOOTH	HIGH	290	115	41
IMGHC	SMOOTH	HIGH	310	118	42
IMGHC	SMOOTH	HIGH	330	121	43
IMGHC	SMOOTH	HIGH	350	126	44
IMGHC	SMOOTH	HIGH	390	128	45
IMGHC	SMOOTH	HIGH	430	135	46
IMGHC	SMOOTH	HIGH	470	142	47
IMGHC	SMOOTH	HIGH	510	146	48
IMGHC	SMOOTH	HIGH	570	151	49
IMGHC	SMOOTH	HIGH	620	157	50
IMGHC	SMOOTH	HIGH	680	160	51

Cologne, 2004-03-15



G. Viola
D. G. Viola

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Doc. 3/12, Rev. 0

**TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln**

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Manufacturer

**Poly Implant Prothèses
337 Avenue de Bruxelles
83507 La Seyne s/Mer Cedex
France**

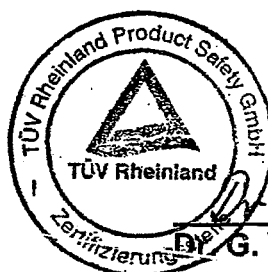
Scope:

Mammary Implants

IMGHC-LS-UH : Smooth surface Ultra-High profile High cohesivity gel pre-filled breast implants

CODE	SURFACE	PROFILE	VOLUME (cc)	DIAMETER (mm)	PROJECTION (mm)
IMGHC	SMOOTH	ULTRA-HIGH	245	101	50
IMGHC	SMOOTH	ULTRA-HIGH	265	104	51
IMGHC	SMOOTH	ULTRA-HIGH	295	107	53
IMGHC	SMOOTH	ULTRA-HIGH	335	112	54
IMGHC	SMOOTH	ULTRA-HIGH	365	116	56
IMGHC	SMOOTH	ULTRA-HIGH	405	120	58
IMGHC	SMOOTH	ULTRA-HIGH	425	123	60
IMGHC	SMOOTH	ULTRA-HIGH	495	128	62

Cologne, 2004-03-15



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Doc. 4/12, Rev. 0

**TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln**

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Report No.: 21111398 004

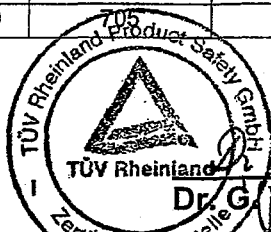
Manufacturer Poly Implant Prothèses
337 Avenue de Bruxelles
83507 La Seyne s/Mer Cedex
France

Scope: Mammary Implants

MGHC-MX-S : Micro-Textured surface Standard profile High cohesivity gel pre-filled breast implants

CODE	SURFACE	PROFILE	VOLUME (cc)	DIAMETER (mm)	PROJECTION (mm)
IMGHC	MICROTEXTURED	STANDARD	85	87	18
IMGHC	MICROTEXTURED	STANDARD	105	92	20
IMGHC	MICROTEXTURED	STANDARD	125	97	21
IMGHC	MICROTEXTURED	STANDARD	145	102	23
IMGHC	MICROTEXTURED	STANDARD	165	106	26
IMGHC	MICROTEXTURED	STANDARD	185	108	27
IMGHC	MICROTEXTURED	STANDARD	205	110	28
IMGHC	MICROTEXTURED	STANDARD	225	114	29
IMGHC	MICROTEXTURED	STANDARD	245	117	30
IMGHC	MICROTEXTURED	STANDARD	265	124	31
IMGHC	MICROTEXTURED	STANDARD	285	126	32
IMGHC	MICROTEXTURED	STANDARD	305	128	33
IMGHC	MICROTEXTURED	STANDARD	325	130	34
IMGHC	MICROTEXTURED	STANDARD	345	132	35
IMGHC	MICROTEXTURED	STANDARD	365	136	34
IMGHC	MICROTEXTURED	STANDARD	415	141	35
IMGHC	MICROTEXTURED	STANDARD	455	145	36
IMGHC	MICROTEXTURED	STANDARD	505	150	37
IMGHC	MICROTEXTURED	STANDARD	555	156	38
IMGHC	MICROTEXTURED	STANDARD	605	160	39
IMGHC	MICROTEXTURED	STANDARD	655	166	40
IMGHC	MICROTEXTURED	STANDARD	705	172	41

Cologne, 2004-03-15



DUPLIKAT



170

Doc. 5/12, Rev. 0

**TÜV Rheinland
Product Safety GmbH
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**ID 60007598 0001
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Manufacturer

**Poly Implant Prothèses
337 Avenue de Bruxelles
83507 La Seyne s/Mer Cedex
France**

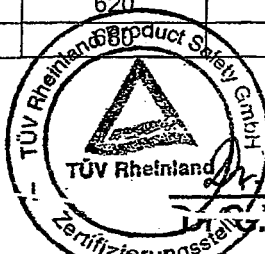
Scope:

Mammary Implants

IMGHC-MX-H : Micro-Textured surface High profile High cohesivity gel pre-filled breast implants

CODE	SURFACE	PROFILE	VOLUME (cc)	DIAMETER (mm)	PROJECTION (mm)
IMGHC	MICROTEXTURED	HIGH	90	80	29
IMGHC	MICROTEXTURED	HIGH	130	84	32
IMGHC	MICROTEXTURED	HIGH	150	90	34
IMGHC	MICROTEXTURED	HIGH	170	94	35
IMGHC	MICROTEXTURED	HIGH	190	98	36
IMGHC	MICROTEXTURED	HIGH	210	102	37
IMGHC	MICROTEXTURED	HIGH	230	105	38
IMGHC	MICROTEXTURED	HIGH	250	109	39
IMGHC	MICROTEXTURED	HIGH	270	112	40
IMGHC	MICROTEXTURED	HIGH	290	115	41
IMGHC	MICROTEXTURED	HIGH	310	118	42
IMGHC	MICROTEXTURED	HIGH	330	121	43
IMGHC	MICROTEXTURED	HIGH	350	126	44
IMGHC	MICROTEXTURED	HIGH	390	128	45
IMGHC	MICROTEXTURED	HIGH	430	135	46
IMGHC	MICROTEXTURED	HIGH	470	142	47
IMGHC	MICROTEXTURED	HIGH	510	146	48
IMGHC	MICROTEXTURED	HIGH	570	151	49
IMGHC	MICROTEXTURED	HIGH	620	157	50
IMGHC	MICROTEXTURED	HIGH		160	51

Cologne, 2004-03-15



Dr. P. Viola
Viola

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Doc. 6/12, Rev. 0

**TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln**

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Registration No.:
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**ID 60007598 0001
21111398 004**

Manufacturer

**Poly Implant Prothèses
337 Avenue de Bruxelles
83507 La Seyne s/Mer Cedex
France**

Scope:

Mammary Implants

IMGHC-MX-UH : Micro-Textured surface Ultra-High profile High cohesivity gel pre-filled breast implants

CODE	SURFACE	PROFILE	VOLUME (cc)	DIAMETER (mm)	PROJECTION (mm)
IMGHC	MICROTEXTURED	ULTRA-HIGH	245	101	50
IMGHC	MICROTEXTURED	ULTRA-HIGH	265	104	51
IMGHC	MICROTEXTURED	ULTRA-HIGH	295	107	53
IMGHC	MICROTEXTURED	ULTRA-HIGH	335	112	54
IMGHC	MICROTEXTURED	ULTRA-HIGH	365	116	56
IMGHC	MICROTEXTURED	ULTRA-HIGH	405	120	58
IMGHC	MICROTEXTURED	ULTRA-HIGH	425	123	60
IMGHC	MICROTEXTURED	ULTRA-HIGH	495	128	62

Cologne, 2004-03-15



DUPLIKAT



168

Doc. 7/12, Rev. 0

**TÜV Rheinland
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Am Grauen Stein, D-51105 Köln**

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Manufacturer

**Poly Implant Prothèses
337 Avenue de Bruxelles
83507 La Seyne s/Mer Cedex
France**

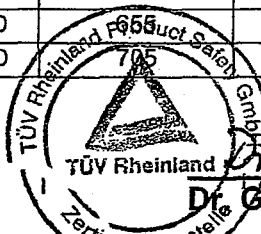
Scope:

Mammary Implants

MGHC-TX-S : Textured surface Standard profile High cohesivity gel pre-filled breast implants

CODE	SURFACE	PROFILE	VOLUME (cc)	DIAMETER (mm)	PROJECTION (mm)
IMGHC	TEXTURED	STANDARD	85	87	18
IMGHC	TEXTURED	STANDARD	105	92	20
IMGHC	TEXTURED	STANDARD	125	97	21
IMGHC	TEXTURED	STANDARD	145	102	23
IMGHC	TEXTURED	STANDARD	165	106	26
IMGHC	TEXTURED	STANDARD	185	108	27
IMGHC	TEXTURED	STANDARD	205	110	28
IMGHC	TEXTURED	STANDARD	225	114	29
IMGHC	TEXTURED	STANDARD	245	117	30
IMGHC	TEXTURED	STANDARD	265	124	31
IMGHC	TEXTURED	STANDARD	285	126	32
IMGHC	TEXTURED	STANDARD	305	128	33
IMGHC	TEXTURED	STANDARD	325	130	34
IMGHC	TEXTURED	STANDARD	345	132	35
IMGHC	TEXTURED	STANDARD	365	136	34
IMGHC	TEXTURED	STANDARD	415	141	35
IMGHC	TEXTURED	STANDARD	455	145	36
IMGHC	TEXTURED	STANDARD	505	150	37
IMGHC	TEXTURED	STANDARD	555	156	38
IMGHC	TEXTURED	STANDARD	605	160	39
IMGHC	TEXTURED	STANDARD	655	166	40
IMGHC	TEXTURED	STANDARD	705	172	41

Cologne, 2004-03-15



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Doc. 8/12, Rev. 0

**TÜV Rheinland
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Report No.: 21111398 004**

**Manufacturer Poly Implant Prothèses
337 Avenue de Bruxelles
83507 La Seyne s/Mer Cedex
France**

Scope: Mammary Implants

IMGHC-TX-H : Textured surface High profile High cohesivity gel pre-filled breast implants

CODE	SURFACE	PROFILE	VOLUME (cc)	DIAMETER (mm)	PROJECTION (mm)
IMGHC	TEXTURED	HIGH	90	80	29
IMGHC	TEXTURED	HIGH	130	84	32
IMGHC	TEXTURED	HIGH	150	90	34
IMGHC	TEXTURED	HIGH	170	94	35
IMGHC	TEXTURED	HIGH	190	98	36
IMGHC	TEXTURED	HIGH	210	102	37
IMGHC	TEXTURED	HIGH	230	105	38
IMGHC	TEXTURED	HIGH	250	109	39
IMGHC	TEXTURED	HIGH	270	112	40
IMGHC	TEXTURED	HIGH	290	115	41
IMGHC	TEXTURED	HIGH	310	118	42
IMGHC	TEXTURED	HIGH	330	121	43
IMGHC	TEXTURED	HIGH	350	126	44
IMGHC	TEXTURED	HIGH	390	128	45
IMGHC	TEXTURED	HIGH	430	135	46
IMGHC	TEXTURED	HIGH	470	142	47
IMGHC	TEXTURED	HIGH	510	146	48
IMGHC	TEXTURED	HIGH	570	151	49
IMGHC	TEXTURED	HIGH	620	157	50
IMGHC	TEXTURED	HIGH	680	160	51

Cologne, 2004-03-15



Dr. G. Viola
Dr. G. Viola

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Doc. 9/12, Rev. 0

**TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln**

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**Manufacturer Poly Implant Prothèses
337 Avenue de Bruxelles
83507 La Seyne s/Mer Cedex
France**

Scope: Mammary Implants

IMGHC-TX-UH : Textured surface ultra-High profile High cohesivity gel pre-filled breast implants

CODE	SURFACE	PROFILE	VOLUME (cc)	DIAMETER (mm)	PROJECTION (mm)
IMGHC	TEXTURED	ULTRA-HIGH	245	101	50
IMGHC	TEXTURED	ULTRA-HIGH	265	104	51
IMGHC	TEXTURED	ULTRA-HIGH	295	107	53
IMGHC	TEXTURED	ULTRA-HIGH	335	112	54
IMGHC	TEXTURED	ULTRA-HIGH	365	116	56
IMGHC	TEXTURED	ULTRA-HIGH	405	120	58
IMGHC	TEXTURED	ULTRA-HIGH	425	123	60
IMGHC	TEXTURED	ULTRA-HIGH	495	128	62

Cologne, 2004-03-15



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**TÜV Rheinland
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Am Grauen Stein, D-51105 Köln**

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**ID 60007598 0001
21111398 004**

Manufacturer

**Poly Implant Prothèses
337 Avenue de Bruxelles
83507 La Seyne s/Mer Cedex
France**

Scope:

Mammary Implants

IMGHC-TX-R : Textured surface Reconstruction profile High cohesivity gel pre-filled breast implants

CODE	SURFACE	PROFILE	VOLUME (cc)	WIDTH (mm)	HEIGHT (mm)	PROJECTION MAXI (mm)
IMGHC	TEXTURED	RECONSTRUCTION	180	111	96	39
IMGHC	TEXTURED	RECONSTRUCTION	220	113	98	41
IMGHC	TEXTURED	RECONSTRUCTION	260	120	98	44
IMGHC	TEXTURED	RECONSTRUCTION	330	127	111	48
IMGHC	TEXTURED	RECONSTRUCTION	420	132	118	53
IMGHC	TEXTURED	RECONSTRUCTION	500	143	124	57
IMGHC	TEXTURED	RECONSTRUCTION	600	154	137	60

Cologne, 2004-03-15



[Signature]
Dr. G. Viola

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Doc. 11/12, Rev. 0

**TÜV Rheinland
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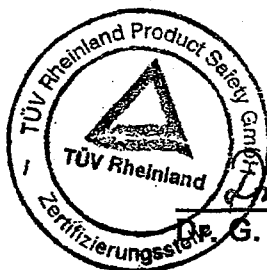
Manufacturer Poly Implant Prothèses
337 Avenue de Bruxelles
83507 La Seyne s/Mer Cedex
France

Scope: Mammary Implants

IMGHC-TX-AL : Textured surface Asymmetrical profile High cohesivity gel pre-filled breast implants – Left side

CODE	SURFACE	PROFILE	VOLUME (cc)	WIDTH(mm)	HEIGHT(mm)	PROJECTION (mm)
IMGHC	TEXTURED	ASYMMETRICAL	200	109	86	36
IMGHC	TEXTURED	ASYMMETRICAL	230	114	89	39
IMGHC	TEXTURED	ASYMMETRICAL	245	119	93	42
IMGHC	TEXTURED	ASYMMETRICAL	260	125	98	44
IMGHC	TEXTURED	ASYMMETRICAL	280	130	102	46
IMGHC	TEXTURED	ASYMMETRICAL	300	135	107	48
IMGHC	TEXTURED	ASYMMETRICAL	330	138	110	50
IMGHC	TEXTURED	ASYMMETRICAL	370	143	115	52
IMGHC	TEXTURED	ASYMMETRICAL	400	148	119	54
IMGHC	TEXTURED	ASYMMETRICAL	450	153	124	56

Cologne, 2004-03-15



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163

Doc. 12/12, Rev. 0

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Manufacturer

**Poly Implant Prothèses
337 Avenue de Bruxelles
83507 La Seyne s/Mer Cedex
France**

Scope:

Mammary Implants

IMGHC-TX-AR : Textured surface Asymmetrical profile High cohesivity gel pre-filled breast implants – Right side

CODE	SURFACE	PROFILE	VOLUME (cc)	WIDTH(mm)	HEIGHT(mm)	PROJECTION (mm)
IMGHC	TEXTURED	ASYMMETRICAL	200	109	86	36
IMGHC	TEXTURED	ASYMMETRICAL	230	114	89	39
IMGHC	TEXTURED	ASYMMETRICAL	245	119	93	42
IMGHC	TEXTURED	ASYMMETRICAL	260	125	98	44
IMGHC	TEXTURED	ASYMMETRICAL	280	130	102	46
IMGHC	TEXTURED	ASYMMETRICAL	300	135	107	48
IMGHC	TEXTURED	ASYMMETRICAL	330	138	110	50
IMGHC	TEXTURED	ASYMMETRICAL	370	143	115	52
IMGHC	TEXTURED	ASYMMETRICAL	400	148	119	54
IMGHC	TEXTURED	ASYMMETRICAL	450	153	124	56

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