

## KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

Name und Adresse der Firma /  
Name and address of the firm

**Heraeus Kulzer GmbH**  
Grüner Weg 11, 63450 Hanau  
Deutschland / Germany

**Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that**

das Medizinprodukt / the medical device

### **Charisma**

Bezeichnung, Typ oder Modell, Chargen-  
oder Seriennummer, ev. Herkunft und  
Stückzahl/ Name, type or model, batch or  
serial number, possibly sources and number  
of items

Zahnärztlicher Füllungswerkstoff, lichthärtend;  
Dental restorative material, light curing;

Artikelliste siehe Anhang/ List of Articles see Annex

Fertigung gemäß Version 1 der Technischen  
Dokumentation von Charisma/ Manufacturing  
according to Technical File of Charisma, Version 1

GMDN-Nummer / GMDN code  
UMDNS-Nummer / UMDNS code

35875  
16-724

der Klasse / of class

Ila

nach Regel / according to rule

8 nach Anhang IX der Richtlinie 93/42/EWG /  
according to Annex IX of Directive 93/42/EEC

**allen Anforderungen der Richtlinie 93/42/EWG entspricht, die anwendbar sind/  
meets all the provisions of the Directive 93/42/EEC which apply to it.**

Angewandte harmonisierte Normen,  
nationale Normen oder andere normative  
Dokumente / Applied harmonised  
standards, national standards or other  
normative documents

EN ISO 4049:2000 Zahnheilkunde - Füllungs-,  
restaurative und Befestigungskunststoffe/ Dentistry -  
Polymer-based filling, restorative and luting materials

Weitere angewandte Normen siehe Version 1 der  
Technischen Dokumentation von Charisma/ Further  
Applied standards see Technical File of Charisma,  
Version 1

Konformitätsbewertungsverfahren  
Conformity assessment procedure

Richtlinie 93/42/EWG Anhang II, Abschnitt 3  
Directive 93/42/EEC Annex II, Section 3

Benannte Stelle / Notified Body

TÜV Rheinland Product Safety GmbH  
Am Grauen Stein, 51105 Köln, CE 0197

Versionsnummer/ Version number:

3

Ersetzt Konformitätserklärung vom/  
Replaces Declaration of Conformity from:

2006-03-28

Hanau, 2007-09-24

i.V. Dr. Martina Hecker   
Ltg. Klin. Forschung + Zulassung  
Head of Clin. Research + Reg. Affairs  
Heraeus Kulzer GmbH

Ort, Datum / Place, date

Name und Funktion / Name and function

## Konformitätserklärung / Declaration of Conformity Anhang / Annex: Artikelliste / List of Articles

Das Medizinprodukt / **Charisma**  
 The medical device  
 Versionsnummer/ Version number: 3  
 Ersetzt Anhang vom/ 2006-03-28  
 Replaces Annex from:

Artikelnummer/ Article number	Artikelbezeichnung/ Article name
66001480	CHARISMA 1 X 4 G, A 10 - JAPAN
66001481	CHARISMA 1 X 4 G, A 20 - JAPAN
66001482	CHARISMA 1 X 4 G, A 30 - JAPAN
66001483	CHARISMA 1 X 4 G, A 35 - JAPAN
66001484	CHARISMA 1 X 4 G, B 20 - JAPAN
66001485	CHARISMA 1 X 4 G, B 30 - JAPAN
66001486	CHARISMA 1 X 4 G, C 20 - JAPAN
66001489	CHARISMA 1 X 4 G, I - JAPAN
66001487	CHARISMA 1 X 4 G, OA 30 - JAPAN
66001488	CHARISMA 1 X 4 G, OB 20 - JAPAN
66020000	CHARISMA A2 2 PLT SAMPLE
66016412	CHARISMA ASSORTMENT BUNDLE
66005911	CHARISMA BULK 1 GR A1
66005912	CHARISMA BULK 1 GR A2
66005913	CHARISMA BULK 1 GR A3
66005914	CHARISMA BULK 1 GR A3,5
66005915	CHARISMA BULK 1 GR A4
66005916	CHARISMA BULK 1 GR B1
66005917	CHARISMA BULK 1 GR B2
66005918	CHARISMA BULK 1 GR B3
66005919	CHARISMA BULK 1 GR C2
66005920	CHARISMA BULK 1 GR C3

	<b>Artikelbezeichnung/ Article name</b>
66005921	CHARISMA BULK 1 GR C4
66005922	CHARISMA BULK 1 GR D3
66005933	CHARISMA BULK 1 GR DB
66005927	CHARISMA BULK 1 GR I
66005923	CHARISMA BULK 1 GR OA2
66005924	CHARISMA BULK 1 GR OA3
66005925	CHARISMA BULK 1 GR OA3,5
66005926	CHARISMA BULK 1 GR OB2
66005928	CHARISMA BULK 1 GR SL
66005930	CHARISMA BULK 1 GR SLO
66005931	CHARISMA BULK 1 GR SLT
66005932	CHARISMA BULK 1 GR YB
66016472	CHARISMA BUNDLE A2 PLT
66016423	CHARISMA BUNDLE A2 SYR
66002508	CHARISMA PLT 1 X 10 X 0,25G - CG
66002507	CHARISMA PLT 1 X 10 X 0,25G - DB
66000119	CHARISMA PLT 1 X 10 X 0,25G - I
66000115	CHARISMA PLT 1 X 10 X 0,25G - OA2
66000116	CHARISMA PLT 1 X 10 X 0,25G - OA3
66000117	CHARISMA PLT 1 X 10 X 0,25G - OA3,5
66000118	CHARISMA PLT 1 X 10 X 0,25G - OB2
66000120	CHARISMA PLT 1 X 10 X 0,25G - SL
66002502	CHARISMA PLT 1 X 10 X 0,25G - SL1
66002505	CHARISMA PLT 1 X 10 X 0,25G - SL4
66002504	CHARISMA PLT 1 X 10 X 0,25G - SLO
66002503	CHARISMA PLT 1 X 10 X 0,25G - SLT
66002506	CHARISMA PLT 1 X 10 X 0,25G - YB
66000103	CHARISMA PLT 2 X 10 X 0,25G - A1

66000104	CHARISMA PLT 2 X 10 X 0,25G - A2	
66000105	CHARISMA PLT 2 X 10 X 0,25G - A3	
66000106	CHARISMA PLT 2 X 10 X 0,25G - A3,5	
66000107	CHARISMA PLT 2 X 10 X 0,25G - A4	
66000108	CHARISMA PLT 2 X 10 X 0,25G - B1	
66000109	CHARISMA PLT 2 X 10 X 0,25G - B2	
66000110	CHARISMA PLT 2 X 10 X 0,25G - B3	
66000111	CHARISMA PLT 2 X 10 X 0,25G - C2	
66000112	CHARISMA PLT 2 X 10 X 0,25G - C3	
66000113	CHARISMA PLT 2 X 10 X 0,25G - C4	
66000114	CHARISMA PLT 2 X 10 X 0,25G - D3	
66000078	CHARISMA PLT ASSORTMENT 8 X 10 X 0,25G	
66001692	CHARISMA PLT/GLUMA COMF BOND TRIAL KIT	
66001693	CHARISMA PLT/GLUMA COMFORT BOND COMBI	
66000084	CHARISMA PLT / GLUMA ONE BOND COMBI	
66000082	CHARISMA PLT / GLUMA SOLID BOND COMBI	
66013211	CHARISMA PLT/IBOND TRIAL KIT	
65572125	CHARISMA PLT SAMPLE 1X4X0,25G - A2	
66006690	CHARISMA PROMOTION - KIT	
66000085	CHARISMA SYR 1 X 4G - A1	
66003770	CHARISMA SYR 1 X 4G - A1	REGIO
66000086	CHARISMA SYR 1 X 4G - A2	
66003771	CHARISMA SYR 1 X 4G - A2	REGIO
66000087	CHARISMA SYR 1 X 4G - A3	
66000088	CHARISMA SYR 1 X 4G - A3,5	
66003773	CHARISMA SYR 1 X 4G - A3,5	REGIO
66003772	CHARISMA SYR 1 X 4G - A3	REGIO
66000089	CHARISMA SYR 1 X 4G - A4	
66006113	CHARISMA SYR 1 X 4G - A4	REGIO
66000090	CHARISMA SYR 1 X 4G - B1	

66003774	CHARISMA SYR 1 X 4G - B1	REGIO
66000091	CHARISMA SYR 1 X 4G - B2	
66003775	CHARISMA SYR 1 X 4G - B2	REGIO
66000092	CHARISMA SYR 1 X 4G - B3	
66003776	CHARISMA SYR 1 X 4G - B3	REGIO
66000093	CHARISMA SYR 1 X 4G - C2	
66003777	CHARISMA SYR 1 X 4G - C2	REGIO
66000094	CHARISMA SYR 1 X 4G - C3	
66006114	CHARISMA SYR 1 X 4G - C3	REGIO
66000095	CHARISMA SYR 1 X 4G - C4	
66006115	CHARISMA SYR 1 X 4G - C4	REGIO
66002515	CHARISMA SYR 1 X 4G - CG	
66000096	CHARISMA SYR 1 X 4G - D3	
66006116	CHARISMA SYR 1 X 4G - D3	REGIO
66002514	CHARISMA SYR 1 X 4G - DB	
66006117	CHARISMA SYR 1 X 4G - DB	REGIO
66000101	CHARISMA SYR 1 X 4G - I	
66003779	CHARISMA SYR 1 X 4G - I	REGIO
66000097	CHARISMA SYR 1 X 4G - OA2	
66003778	CHARISMA SYR 1 X 4G - OA2	REGIO
66000098	CHARISMA SYR 1 X 4G - OA3	
66000099	CHARISMA SYR 1 X 4G - OA3,5	
66006119	CHARISMA SYR 1 X 4G - OA3,5	REGIO
66006118	CHARISMA SYR 1 X 4G - OA3	REGIO
66000100	CHARISMA SYR 1 X 4G - OB2	
66006120	CHARISMA SYR 1 X 4G - OB2	REGIO
66000102	CHARISMA SYR 1 X 4G - SL	
66002509	CHARISMA SYR 1 X 4G - SL1	
66002512	CHARISMA SYR 1 X 4G - SL4	
66002511	CHARISMA SYR 1 X 4G - SLO	

66006122	CHARISMA SYR 1 X 4G - SLO	REGIO
66006121	CHARISMA SYR 1 X 4G - SL	REGIO
66002510	CHARISMA SYR 1 X 4G - SLT	
66006123	CHARISMA SYR 1 X 4G - SLT	REGIO
66002513	CHARISMA SYR 1 X 4G - YB	
66006124	CHARISMA SYR 1 X 4G - YB	REGIO
66009641	CHARISMA SYR 50 X 1G - A2	
66009642	CHARISMA SYR 50 X 1G - OA2	
66009749	CHARISMA SYR 50X ( 1X4 G ) A1	
66009659	CHARISMA SYR 50X ( 1X4 G ) A2	
66009745	CHARISMA SYR 50X ( 1X4 G ) A3	
66009746	CHARISMA SYR 50X ( 1X4 G ) A3,5	
66009767	CHARISMA SYR 50X ( 1X4 G ) A4	
66009761	CHARISMA SYR 50X ( 1X4 G ) B1	
66009748	CHARISMA SYR 50X ( 1X4 G ) B2	
66009763	CHARISMA SYR 50X ( 1X4 G ) B3	
66009764	CHARISMA SYR 50X ( 1X4 G ) C2	
66009769	CHARISMA SYR 50X ( 1X4 G ) C3	
66009768	CHARISMA SYR 50X ( 1X4 G ) C4	
66014451	CHARISMA SYR 50X ( 1X4 G ) D3	
66014452	CHARISMA SYR 50X ( 1X4 G ) DB	
66009762	CHARISMA SYR 50X ( 1X4 G ) I	
66009747	CHARISMA SYR 50X ( 1X4 G ) OA2	
66009750	CHARISMA SYR 50X ( 1X4 G ) OA3	
66009765	CHARISMA SYR 50X ( 1X4 G ) OA3,5	
66009766	CHARISMA SYR 50X ( 1X4 G ) OB2	
66014453	CHARISMA SYR 50X ( 1X4 G ) SL	
66013916	CHARISMA SYR 50X ( 1X4 G ) SLO	
66013917	CHARISMA SYR 50X ( 1X4 G ) SLT	
66014454	CHARISMA SYR 50X ( 1X4 G ) YB	

66000077	CHARISMA SYR ASSORTMENT 8 X 4G
66003734	CHARISMA SYR ASSORTMENT 8 X 4G REGIO
66001491	CHARISMA SYR ECO ASSORTMENT 4 X 4G
66003736	CHARISMA SYR ECO ASSORTMENT 4X4G REGIO
66001690	CHARISMA SYR/GLUMA COMF BOND TRIAL KIT
66003737	CHARISMA SYR/GLUMA COMFORT B.COMBI REGIO
66001691	CHARISMA SYR/GLUMA COMFORT BOND COMBI
66000083	CHARISMA SYR / GLUMA ONE BOND COMBI
66000081	CHARISMA SYR / GLUMA SOLID BOND COMBI
66013208	CHARISMA SYR/IBOND TRIAL KIT
65564815	CHARISMA SYR SAMPLE 1X1G - A2
66005156	CHARISMA SYR SORTIMENT 8X4G REGIO-OE-1
66005157	CHARISMA SYR SORTIMENT 8X4G REGIO-OE-2
66005158	CHARISMA SYR SORTIMENT 8X4G REGIO-OE-3
66005159	CHARISMA SYR SORTIMENT 8X4G REGIO-OE-4
66005161	CHARISMA SYR SORTIMENT 8X4G REGIO-OE-5
66008542	CHARISMA SYR SORTIMENT 8X4G REGIO-OE-6
66022053	CHARISMA SYR/GLUMA C.B.TRIAL KIT REGIO
66035641	CHARISMA SYR/GLUMA CB+D COMBI REGIO

Hanau, 2007-09-24

i.V. Dr. Martina Hecker   
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