
Article 22 Declaration according Medical Device Regulation (EU) 2017/745

We

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau
 Deutschland / Germany

Actor ID: to be defined

herewith declare that,

the medical devices, that are combined in the procedure pack:

CHARISMA DIAMOND ONE KIT

Basic-UDI-DI: ++J014PPCDGBUYW

are mutually compatible according to their intended purpose. The mutual compatibility of the medical devices has been verified in accordance with the manufacturers' instructions and the activities have been carried out in accordance with those instructions;

we packaged the procedure pack and supplied relevant information to users incorporating the information to be supplied by Kulzer as the manufacturer of the mentioned devices which have been put together;

the activity of combining devices and, if applicable, other products as a procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

<i>Version number</i>	01
<i>Replaces Article 22 Declaration from</i>	NA

Hanau, Nov 30, 2022

i.V.


 Dr. Matthias Hartmann
 Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Ort, Datum / Place, date

Name and function

This article 22 declaration is valid in connection with the release documents for the respective batch of produced devices.

List of Articles
Annex to Article 22 Declaration

for the Procedure Pack	CHARISMA DIAMOND ONE KIT
Version number list of articles	V 01
Replaces list of articles from	n.a
This list of articles is valid for the	V 01
Article 22 Declaration version	

Article name Procedure Pack	Article number	UDI-DI
CHARISMA DIAMOND ONE KIT	66087171	+J014660871710
Combined of the following medical devices:		
Article name Combined Products	Article number	UDI-DI
PROC Charisma Diamond ONE Kit 2x4G SYR	66096093	+J014660960930
PROC GLUMA Bond Universal ONE Kit 1x4ML	66096107	+J014660961070

Hanau, Nov 30, 2022

Ort, Datum / Place, date

i.V.

Dr. Matthias Hartmann
 Head of Global Quality, Regulatory & Scientific Services
Kulzer GmbH

Name und Funktion / Name and function


Abschlusszertifikat

Umschlag-ID: B0931849C5284C0EAB12B8020ED2DA58	Status: Abgeschlossen
Betreff: Mit DocuSign abschließen: Charisma Diamond Article 22.pdf	
Quellumschlag:	
Dokumentenseiten: 2	Signaturen: 2
Zertifikatsseiten: 4	Initialen: 0
Signatur mit Anleitung: Aktiviert	Umschlagsteller:
Umschlag-ID-Stempel: Aktiviert	Anette Stadtfeld
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Eintragsverfolgung

Status: Original	Inhaber: Anette Stadtfeld	Standort: DocuSign
30.11.2022 08:04:08	Anette.Stadtfeld@kulzer-dental.com	

Unterzeichnereignisse**Signatur****Zeitstempel**

Matthias Hartmann		Gesendet: 30.11.2022 08:04:53
matthias.hartmann@kulzer-dental.com		Eingesehen: 30.11.2022 08:19:39
PRRC		Signiert: 30.11.2022 08:19:55
Sicherheitsstufe: E-Mail, Kontoauthentifizierung (keine)	Signaturübernahme: Hochgeladenes Signaturbild Mit IP-Adresse: 89.246.249.146	

Vereinbarung bezüglich elektronischer Unterlagen und Signaturen:

Akzeptiert: 30.11.2022 08:19:39
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Notarereignisse	Signatur	Zeitstempel
Umschlagereignisse – Überblick	Status	Zeitstempel
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Zertifiziert zugestellt	Sicherheitsprüfung ausgeführt	30.11.2022 08:19:39
Signiervorgang abgeschlossen	Sicherheitsprüfung ausgeführt	30.11.2022 08:19:55
Abgeschlossen	Sicherheitsprüfung ausgeführt	30.11.2022 08:19:55
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