

EU-Konformitätserklärung
EU declaration of conformity
 Accu-Chek Softclix and CoaguChek Softclix *lancing device*
 Rev. 01

Hersteller
Manufacturer



Roche Diabetes Care GmbH
 Sandhofer Strasse 116
 68305 Mannheim
 Germany

Einmalige Registrierungsnummer (SRN)	n.a.
Single Registration Number (SRN)	n.a.

Wir, Roche Diabetes Care GmbH, tragen die alleinige Verantwortung für die Ausstellung dieser EU-Konformitätserklärung.

This EU declaration of conformity is issued under the sole responsibility of Roche Diabetes Care GmbH.

Produktinformation
Product information

Basis UDI-DI	4015630LD06715YE
Basic UDI-DI	

Produkt- und Handelsname	REF	Katalognummer
Product and trade name		Catalogue number
Accu-Chek Softclix <i>lancing device</i>		n.a.
CoaguChek XS Softclix <i>lancing device</i>		n.a.

Zweckbestimmung Intended purpose	The Accu-Chek Softclix and CoaguChek XS Softclix lancing device is each a device for simple, virtually pain-free collection of capillary blood from the fingertips. The Accu-Chek Softclix and CoaguChek Softclix lancing device is intended for single patient use only! It is only allowed to be used to obtain blood from one person.
Risikoklasse Risk Class	I
Klassifizierungsregel, gemäß Anhang VIII Classification rule, in accordance with Annex VIII	Rule 1, Rule 13
<p>Die von dieser Erklärung erfassten Medizinprodukte entsprechen den folgenden Rechtsvorschriften der Europäischen Union: The devices covered by this EU declaration of conformity are in conformity with the below European Legislations.</p>	
<p>Rechtsvorschriften der Europäischen Union European Union Legislations</p>	
Verordnung (EU) 2017/745 über Medizinprodukte	Regulation (EU) 2017/745 on medical devices
<p>Details zum Konformitätsbewertungsverfahren nach Verordnung (EU) 2017/745: Details on the Conformity Assessment Procedure according to Regulation (EU) 2017/745:</p>	
Durchgeführtes Konformitätsbewertungsverfahren Performed Conformity Assessment Procedure	Gemäß Art. 19 2017/745 According Art. 19 2017/745
Bescheinigung Certificate	EN ISO 13485 Qualitätsmanagementsystem Quality management system

Mannheim, 24 June 2020

Roche Diabetes Care GmbH

i.V./on behalf of the company



Dr. Alexander Rügner

Leiter Regulatory Affairs Mannheim OUS
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Head of Regulatory Affairs Mannheim OUS
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Dr. Thomas Schmidt

Leiter DC Qualität Mannheim
Head of DC Quality Mannheim

Anhang / **Attachment:**

List of components and Kits/Sets of the Accu-Chek Softclix and CoaguChek XS Softclix *lancing device*

Die in der EU-Konformitätserklärung für die Accu-Chek und CoaguChek XS Softclix *lancing device* gelisteten Produkte werden als Bulk-Ware in verschiedene Verpackungskonfigurationen beige packt; siehe untenstehende Liste

The products listed in the EU declaration of conformity for the Accu-Chek and CoaguChek XS Softclix *lancing device* are packed into several package configurations as bulk device, see list below

Produkt -und Handelsname Product and trade name	Katalognummer Catalogue number
Accu-Chek Softclix <i>lancing device, bulk 100</i>	04536398
Accu-Chek Softclix <i>lancing device, bulk 100</i>	04368851
Accu-Chek Softclix <i>lancing device, bulk 100</i>	05181186
CoaguChek XS Softclix <i>lancing device, bulk 100</i>	06535569
CoaguChek XS Softclix <i>lancing device, bulk 100</i>	07313462