

EG-Konformitätserklärung / EC Declaration of Conformity

Hersteller / Manufacturer: Roche Diabetes Care GmbH

Adresse / Address: Sandhofer Strasse 116
68305 Mannheim
Germany

Roche Diabetes Care GmbH erklärt unter seiner alleinigen Verantwortung, dass das Produkt / die Produktfamilie

Roche Diabetes Care GmbH declares under its sole responsibility that the product / family of products

Produktname / Product name:

Accu-Chek® Spirit Combo Insulin Pump

Beschreibung / Description:

Tragbare, batteriebetriebene Insulinpumpe mit Bluetooth-Schnittstelle zur Verwendung mit einer Fernbedienung (als Zubehör) für kontinuierliche subkutane Infusion von U100-Insulin, oder für kontinuierliche intraperitoneale Infusion von U100-Insulin in Kombination mit dem Accu-Chek® DiaPort System, mit variablen Basalraten für den Gebrauch von 3,15 ml Glas- oder Kunststoff-ampullen.

Portable, battery-operated insulin pump for use with a remote control (as an accessory) for continuous subcutaneous infusion of insulin U100, or for continuous intraperitoneal infusion of insulin U100 in combination with the Accu-Chek® DiaPort System, with variable basal rates for use with 3.15 ml glass or plastic cartridges.

auf das / die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte in ihrer jeweils gültigen Fassung entspricht; gemäß Anhang II der Richtlinie als Konformitätsbewertungsverfahren unter Beteiligung der Benannten Stelle TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München mit der Nummer 0123 angewandt.

to which this declaration relates, complies with the EC Directive 93/42/EEC of June 14, 1993 on medical devices, as amended, using Annex II as the conformity assessment procedure with the involvement of TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München (NB 0123) as the Notified Body was followed.

Die oben aufgeführten Medizinprodukte sind gemäß Artikel 9 der EG-Richtlinie 93/42/EWG als Medizinprodukte der Klasse IIb klassifiziert.

The above mentioned medical devices are classified according Article 9 of the EC Directive 93/42/EEC as Class IIb Medical Devices.

Diese EG Konformitätserklärung ist für alle oben aufgeführte Produkte gültig, die ab dem 29. März 2019 in Verkehr gebracht werden bis zur Ausstellung einer revidierten EG-Konformitätserklärung nach Änderung des Produktes und/oder durch das Ablaufdatum der von der Benannten Stelle ausgestellten Bescheinigung(en).

This EC Declaration of Conformity is valid for all the above mentioned products placed on the market beginning of 29. March 2019 and limited by the issuing of a revised declaration of conformity after change of the product and/or by the expiration date of the certificate(s) issued by the notified body.

Kontaktadresse / Contact address:

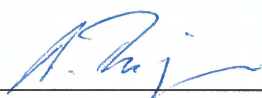
Roche Diabetes Care GmbH
Abt. Qualitätsmanagement
Sandhofer Strasse 116
68305 Mannheim
Germany

Mannheim, 29. März 2019

Roche Diabetes Care GmbH

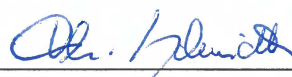
i.V./On behalf of the company

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Dr. Alexander Rügner

Leiter Regulatory Affairs Mannheim
OUS submission und IDS
Head of Regulatory Affairs Mannheim
OUS submission and IDS



Dr. Thomas Schmidt

Leiter DC Qualität Mannheim
Head of DC Quality Mannheim

Anhang/Attachment:

List of Kits containing Accu-Chek® Combo Insulin Pump

Die in der EG-Konformitätserklärung für das Accu-Chek Spirit Combo Insulin Pump gelisteten Produkte werden in verschiedenen Verpackungskonfigurationen sowie in Kombination mit anderen Produkten von Roche Diabetes Care GmbH, als Kit oder Set bezeichnet, in den Verkehr gebracht.

The products listed in the EC Declaration of Conformity are brought on the market in several package configurations as well as in combination with other products from Roche Diabetes Care GmbH, named Kit or Set.

Die Accu-Chek Spirit Combo System Komponenten sind in folgenden Kits enthalten:

The Accu-Chek Spirit Combo system components are packed into the following kits:

Katalognummer Catalog number	Beschreibung Description	Materialnummer und Kitkomponenten Material number and kit components (nur / only MDs und / and IVDs)
05387183	Accu-Chek Combo kit mmol DE /de	05027250001 Accu-Chek Spirit Combo 05075700005 Accu-Chek Aviva Combo 04799062001 Accu-Chek FlexLink Infusion Set 04925742001 Accu-Chek Rapid-D Link 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 06435785001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 05061997001 Accu-Chek Spirit Neoprene pouch white 04545397001 Accu-Chek Spirit Alcantara Pouch black 04652371001 Accu-Chek Belly Belt white
05337062	Accu-Chek Combo kit mmol ROW 1/nl	05027250001 Accu-Chek Spirit Combo 05075700005 Accu-Chek Aviva Combo 04799062001 Accu-Chek FlexLink Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 06435785001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 05061997001 Accu-Chek Spirit Neoprene pouch white
05458862	Accu-Chek Combo kit mmol ROW 1/de	
05458919	Accu-Chek Combo kit mmol ROW 1/fr	
05458927	Accu-Chek Combo kit mmol ROW 1/it	
05387191	Accu-Chek Combo kit mmol ROW 1/en	05027250001 Accu-Chek Spirit Combo 05172594005 Accu-Chek Aviva Combo

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05613248	Accu-Chek Combo kit mmol ROW 2/sl	04799062001 Accu-Chek FlexLink Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 06435785001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 05061997001 Accu-Chek Spirit Neoprene pouch white 04545397001 Accu-Chek Spirit Alcantara Pouch black
05458889	Accu-Chek Combo kit mmol ROW 1/da	05027250001 Accu-Chek Spirit Combo 05075718005 Accu-Chek Aviva Combo 04799062001 Accu-Chek FlexLink Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 06435785001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 05061997001 Accu-Chek Spirit Neoprene pouch white 04545397001 Accu-Chek Spirit Alcantara Pouch black 04652371001 Accu-Chek Belly Belt white
05458897	Accu-Chek Combo kit mmol ROW 1/fi	
05458935	Accu-Chek Combo kit mmol ROW 1/no	
05458943	Accu-Chek Combo kit mmol ROW 1/sv	05027250001 Accu-Chek Spirit Combo 05075718005 Accu-Chek Aviva Combo 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 06435785001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 05061997001 Accu-Chek Spirit Neoprene pouch white 04545397001 Accu-Chek Spirit Alcantara Pouch black 04652371001 Accu-Chek Belly Belt white
05458951	Accu-Chek Combo kit mmol CA 1/en	05027250001 Accu-Chek Spirit Combo 05172594005 Accu-Chek Aviva Combo 04847423001 Accu-Chek Ultraflex Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 06435785001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 05942071001 Accu-Chek Spirit Combo Clip Case
05504708	Accu-Chek Combo kit mmol CA 1/fr	
05359759	Accu-Chek Combo kit mg DE 1/de	05027250001 Accu-Chek Spirit Combo 05075726005 Accu-Chek Aviva Combo 04925742001 Accu-Chek Rapid-D Link 04799062001 Accu-Chek FlexLink Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 06435785001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 05061997001 Accu-Chek Spirit Neoprene pouch

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		white 04545397001 Accu-Chek Spirit Alcantara Pouch black 04652371001 Accu-Chek Belly Belt white
05458501	Accu-Chek Combo kit mg ROW 1/it	05027250001 Accu-Chek Spirit Combo
05458510	Accu-Chek Combo kit mg ROW 1/nl	05075726005 Accu-Chek Aviva Combo
05458498	Accu-Chek Combo kit mg ROW 1/fr	04799062001 Accu-Chek FlexLink Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 06435785001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 05061997001 Accu-Chek Spirit Neoprene pouch white 04545397001 Accu-Chek Spirit Alcantara Pouch black 04652371001 Accu-Chek Belly Belt white
05458480	Accu-Chek Combo kit mg ROW 1/es	05027250001 Accu-Chek Spirit Combo
05458536	Accu-Chek Combo kit mg ROW 1/pt	05151937005 Accu-Chek Aviva Combo 04799062001 Accu-Chek FlexLink Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 06435785001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 05061997001 Accu-Chek Spirit Neoprene pouch white 04545397001 Accu-Chek Spirit Alcantara Pouch black 04652371001 Accu-Chek Belly Belt white
05613264	Accu-Chek Combo kit mg ROW 1/el	05027250001 Accu-Chek Spirit Combo 05151937005 Accu-Chek Aviva Combo 04799062001 Accu-Chek FlexLink Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 07350422001 Accu-Chek Softclix Lancing Device 03157482001 Accu-Chek Softclix (10 Lancets) 05061997001 Accu-Chek Spirit Neoprene pouch white 04545397001 Accu-Chek Spirit Alcantara Pouch black 04652371001 Accu-Chek Belly Belt white
05458544	Accu-Chek Combo kit mg US/en	05027250001 Accu-Chek Spirit Combo 05075645005 Accu-Chek Aviva Combo 04847423001 Accu-Chek Ultraflex Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 06435785001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 05942071001 Accu-Chek Spirit Combo Clip Case

Accu-Chek Performa Combo starter kits

05458579	Accu-Chek Combo kit mmol P-ROW 2/cs	05027250001 Accu-Chek Spirit Combo
05504678	Accu-Chek Combo kit mmol P-ROW 1/en	05075785005 Accu-Chek Performa Combo
		04799062001 Accu-Chek FlexLink Infusion Set
		04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys.
		06435785001 Accu-Chek FastClix Lancing Device
		06436072001 Accu-Chek Fastclix (6 Lancets)
		05061997001 Accu-Chek Spirit Neoprene pouch white
		04545397001 Accu-Chek Spirit Alcantara Pouch black
		04652371001 Accu-Chek Belly Belt white
05899338	Accu-Chek Combo kit mmol P-ROW 2/hu	05027250001 Accu-Chek Spirit Combo
07263457	Accu-Chek Combo kit mmol P-ROW 2/lt	05947120005 Accu-Chek Performa Combo
		04799062001 Accu-Chek FlexLink Infusion Set
		04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys.
		07350422001 Accu-Chek Softclix Lancing Device
		03157482001 Accu-Chek Softclix (10 Lancets)
		05061997001 Accu-Chek Spirit Neoprene pouch white
		04545397001 Accu-Chek Spirit Alcantara Pouch black
		04652371001 Accu-Chek Belly Belt white
05899940	Accu-Chek Combo kit mmol P-ROW 2/ru	05027250001 Accu-Chek Spirit Combo
		05947120005 Accu-Chek Performa Combo
		04799062001 Accu-Chek FlexLink Infusion Set
		04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys.
		05061997001 Accu-Chek Spirit Neoprene pouch white
		04545397001 Accu-Chek Spirit Alcantara Pouch black
		04652371001 Accu-Chek Belly Belt white
05458463	Accu-Chek Combo kit mg P-ROW 1/fr	05027250001 Accu-Chek Spirit Combo
		05075815005 Accu-Chek Performa Combo
		04799062001 Accu-Chek FlexLink Infusion Set
		04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys.
		06435785001 Accu-Chek FastClix Lancing Device
		06436072001 Accu-Chek Fastclix (6 Lancets)
		05061997001 Accu-Chek Spirit Neoprene pouch white
		04545397001 Accu-Chek Spirit Alcantara Pouch black
		04652371001 Accu-Chek Belly Belt white

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05458455	Accu-Chek Combo kit mg P-ROW 1/de	05027250001 Accu-Chek Spirit Combo 05075815005 Accu-Chek Performa Combo 04799062001 Accu-Chek FlexLink Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 05061997001 Accu-Chek Spirit Neoprene pouch white 04545397001 Accu-Chek Spirit Alcantara Pouch black 04652371001 Accu-Chek Belly Belt white
05520932	Accu-Chek Combo kit mg P-BR/pt	05027250001 Accu-Chek Spirit Combo
05877199	Accu-Chek Combo kit mg P-ROW 1/es	05151961006 Accu-Chek Performa Combo 04799062001 Accu-Chek FlexLink Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 06435785001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 05061997001 Accu-Chek Spirit Neoprene pouch white 04545397001 Accu-Chek Spirit Alcantara Pouch black 04652371001 Accu-Chek Belly Belt white
05877164	Accu-Chek Combo kit mg P-ROW 1/en	05027250001 Accu-Chek Spirit Combo
07353413	Accu-Chek Combo kit mg P-ROW 1/ar	05151961006 Accu-Chek Performa Combo 04799062001 Accu-Chek FlexLink Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 05061997001 Accu-Chek Spirit Neoprene pouch white 04545397001 Accu-Chek Spirit Alcantara Pouch black 04652371001 Accu-Chek Belly Belt white
05899222	Accu-Chek Combo Kit mg P-ROW 2/pl	05027250001 Accu-Chek Spirit Combo 05947138005 Accu-Chek Performa Combo 04799062001 Accu-Chek FlexLink Infusion Set 04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys. 06435785001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 05061997001 Accu-Chek Spirit Neoprene pouch white 04545397001 Accu-Chek Spirit Alcantara Pouch black 04652371001 Accu-Chek Belly Belt white
08366306	Accu-Chek Combo Kit mmol P-AU/en	05027250001 Accu-Chek Spirit Combo 05075785005 Accu-Chek Performa Combo 07531656001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets)

Accu-Chek Spirit Combo Starter Kits

Katalognummer Catalog number	Beschreibung Description	Materialnummer und Kitkomponenten Material number and kit components (nur / only MDs und / and IVDs)
05899249	Accu-Chek Spirit Combo kit ROW 2/sk	05027250001 Accu-Chek Spirit Combo
05899257	Accu-Chek Spirit Combo kit ROW 2/ro	04799062001 Accu-Chek FlexLink Infusion Set
06544584	Accu-Chek Spirit Combo kit ROW 2/ru	04949064001 Accu-Chek Spirit 3.15 ml Cartridge Sys.
06612164	Accu-Chek Spirit Combo kit ROW 2/pl	05061997001 Accu-Chek Spirit Neoprene pouch white
		04545397001 Accu-Chek Spirit Alcantara Pouch black
		04652371001 Accu-Chek Belly Belt white

Accu-Chek Spirit Combo Starter Kits Light

Katalognummer Catalog number	Beschreibung Description	Materialnummer und Kitkomponenten Material number and kit components (nur / only MDs und / and IVDs)
08225826	Accu-Chek Spirit Combo Kit Light SK/sk	05027250001 Accu-Chek Spirit Combo
08433283	Accu-Chek Spirit Combo Kit Light RU/ru	
08225770	Accu-Chek Spirit Combo Kit Light FI/fi	
07870116	Accu-Chek Combo Kit Light mg P-PL/pl	05027250001 Accu-Chek Spirit Combo
07870442	Accu-Chek Spirit Combo Kit Light RO/ro	05947138005 Accu-Chek Performa Combo
07876521	Accu-Chek Combo Kit Light mmol CH/de	05027250001 Accu-Chek Spirit Combo
07870507	Accu-Chek Combo Kit Light mmol CH/fr	05075700005 Accu-Chek Aviva Combo
07870515	Accu-Chek Combo Kit Light mmol CH/it	06435785001 Accu-Chek FastClix Lancing Device
		06436072001 Accu-Chek Fastclix (6 Lancets)
07870434	Accu-Chek Combo Kit Light mg US/en	05027250001 Accu-Chek Spirit Combo
		05075645005 Accu-Chek Aviva Combo
		06435785001 Accu-Chek FastClix Lancing Device
		06436072001 Accu-Chek Fastclix (6 Lancets)
08153400	Accu-Chek Combo Kit Light mmol P-RU/ru	05027250001 Accu-Chek Spirit Combo
		05947120005 Accu-Chek Performa Combo
08225761	Accu-Chek Combo Kit Light mg A-ES/es	05027250001 Accu-Chek Spirit Combo
		05151937005 Accu-Chek Aviva Combo
07870493	Accu-Chek Combo Kit Light mg GR/el	07531656001 Accu-Chek FastClix Lancing Device
08306532	Accu-Chek Combo Kit Light mg A-PT/pt	06436072001 Accu-Chek Fastclix (6 Lancets)
08225818	Accu-Chek Combo Kit Light mmol A-DK/da	05027250001 Accu-Chek Spirit Combo
08225834	Accu-Chek Combo Kit Light mmol A-SE/sv	05075718005 Accu-Chek Aviva Combo
		07531656001 Accu-Chek FastClix Lancing Device
08433232	Accu-Chek Combo Kit Light mmol A-FI/fi	06436072001 Accu-Chek Fastclix (6 Lancets)
08225788	Accu-Chek Combo Kit Light mg A-IT/it	05027250001 Accu-Chek Spirit Combo
		05075726005 Accu-Chek Aviva Combo
08225877	Accu-Chek Combo Kit Light mg A-BE/nl	07531656001 Accu-Chek FastClix Lancing Device
08227314	Accu-Chek Combo Kit Light mg A-LU/fr	06436072001 Accu-Chek Fastclix (6 Lancets)

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08012938	Accu-Chek Combo Kit Light mg DE/de	
07870159	Accu-Chek Combo Kit Light mmol SI/sl	05027250001 Accu-Chek Spirit Combo 05172594005 Accu-Chek Aviva Combo 07531656001 Accu-Chek FastClix Device 06436072001 Accu-Chek Fastclix 6 Lancet Drum
07920458	Accu-Chek Combo Kit Light mmol UK/en	
08012954	Accu-Chek Combo Kit Light mmol DE/de	05027250001 Accu-Chek Spirit Combo 05075700005 Accu-Chek Aviva Combo 07531656001 Accu-Chek FastClix Device 06436072001 Accu-Chek Fastclix 6 Lancet Drum
08013870	Accu-Chek Combo Kit Light mmol NL/nl	05027250001 Accu-Chek Spirit Combo 05075700005 Accu-Chek Aviva Combo
08225796	Accu-Chek Combo Kit Light mg P-AR/es	05027250001 Accu-Chek Spirit Combo 05151961006 Accu-Chek Performa Combo 07531656001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets)
08225842	Accu-Chek Combo Kit Light mg P-ROW 1/en	
08173435	Accu-Chek Combo Kit Light mg P-UAE/ar	
07870132	Accu-Chek Combo Kit Light mg P-BR/pt	
08925038	Accu-Chek Combo Kit mg P MX/es	05027250001 Accu-Chek Spirit Combo 05151961006 Accu-Chek Performa Combo 07350422001 Accu-Chek Softclix Lancing device 03157482001 Accu-Chek Softclix (10 lancets)
08225869	Accu-Chek Combo Kit Light mmol P-HU/hu	05027250001 Accu-Chek Spirit Combo 05947120005 Accu-Chek Performa Combo 07350422001 Accu-Chek Softclix Lancing device 03157482001 Accu-Chek Softclix (10 lancets)
08651922	Accu-Chek Combo Kit Light mmol P-LV/lv	
08225885	Accu-Chek Combo Kit Light mg P-FR/fr	05027250001 Accu-Chek Spirit Combo 05075815005 Accu-Chek Performa Combo 07531656001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets)
08225893	Accu-Chek Combo Kit Light mg P-AT/de	05027250001 Accu-Chek Spirit Combo 05075815005 Accu-Chek Performa Combo
08225907	Accu-Chek Combo Kit Light mmol P-CZ/cs	05027250001 Accu-Chek Spirit Combo 05075785005 Accu-Chek Performa Combo 07531656001 Accu-Chek FastClix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets)
07920415	Accu-Chek Combo Kit Light mmol P-ROW1/en	
07917694	Accu-Chek Combo Kit Light mmol P-LT/lt	05027250001 Accu-Chek Spirit Combo 05947120005 Accu-Chek Performa Combo 07350422001 Accu-Chek Softclix device, black 03157482001 Accu-Chek Softclix (10 lancets)
08433232	Accu-Chek Combo Kit Light mmol A-FI/fi	05027250001 Accu-Chek Spirit Combo

Accu-Chek Spirit Combo Backup Kit

Katalognummer Catalog number	Beschreibung Description	Materialnummer und Kitkomponenten Material number and kit components (nur / only MDs und / and IVDs)
05391814	Accu-Chek Spirit Combo backup DE/de	05027250001 Accu-Chek Spirit Combo
05391822	Accu-Chek Spirit Combo backup ROW1	

Accu-Chek Spirit Combo Replacement Kit

Katalognummer Catalog number	Beschreibung Description	Materialnummer und Kitkomponenten Material number and kit components (nur / only MDs und / and IVDs)
05391547	Accu-Chek Spirit Combo Repl. DE/de	05027250001 Accu-Chek Spirit Combo
05391512	Accu-Chek Spirit Combo Repl. US/en	
07993854	Accu-Chek Spirit Combo Repl. AU/en	
05344522	Accu-Chek Spirit Combo Repl. ROW 1	
05391482	Accu-Chek Spirit Combo Repl. ROW 2	
06377297	Accu-Chek Spirit Combo Repl. BR/pt	
08402833	Accu-Chek Spirit Combo Repl. AR/es	