EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 711083**

Issued To: **Ascensia Diabetes Care Holdings AG**
Peter Merian-Strasse 90
Basel
4052
Switzerland

In respect of:

The design, development and manufacture of blood glucose measuring systems for home and professional use, including meters, test strips, control solutions and urine test-strips for self-testing.

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-07-11** Date: **2021-08-06** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 711083

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Number	Device Name	Intended purpose per IFU
Annex II List B		
IVD 0309	CONTOUR XT blood glucose meter	The blood glucose meters are intended for self-testing by persons with diabetes and by healthcare professional to monitor glucose concentrations in fresh capillary whole blood drawn from the fingertip, arterial and venous whole blood or neonatal blood**. **except CONTOUR and CONTOUR TS which are not intended for neonatal use. The meters are not intended for the diagnosis of or screening for diabetes mellitus. The meters are for the quantitative measurement of glucose in whole blood from 0.6 mmol/L to 33.3 mmol/L (10 mg/dL to 600 mg/mL). The system is intended for in vitro diagnostic use only
	CONTOUR NEXT blood glucose meter	
	CONTOUR PLUS blood glucose meter	
	CONTOUR blood glucose meter	
	CONTOUR TS blood glucose meter	

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Number	Device Name	Intended purpose per IFU
Annex II List B		
IVD 0309	CONTOUR NEXT (Connected) blood glucose meter	The blood glucose meters are intended for self-testing by persons with diabetes and by healthcare professional to monitor glucose concentrations in venous blood and/or in fresh capillary whole blood drawn from the fingertip or palm. The meters should not be used for the diagnosis of or screening for diabetes mellitus or for neonatal use. The meters are for the quantitative measurement of glucose in whole blood from 0.6 mmol/L to 33.3 mmol/L (10 mg/dL to 600 mg/mL). The system is intended for in vitro diagnostic use only
	CONTOUR NEXT ONE blood glucose meter	
	CONTOUR PLUS ONE blood glucose meter	
	CONTOUR CARE blood glucose meter	
	CONTOUR PLUS BLUE blood glucose meter	
	CONTOUR PLUS ELITE blood glucose meter	
	CONTOUR FIT blood glucose meter	

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Number	Device Name	Intended purpose per IFU
Annex II List B		
IVD 0309	CONTOUR NEXT LINK blood glucose meter	The blood glucose meters are intended for self-testing by persons with diabetes to monitor glucose concentrations for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertip or palm. The meters should not be used for the diagnosis of or screening for diabetes mellitus or for neonatal use. The LINK models are intended to be used to transmit glucose values to Medtronic devices and facilitate transfer of information to Medtronic Carelink® Software through use of radio frequency communication. The system is intended for in vitro diagnostic use only
	CONTOUR NEXT LINK 2.4 blood glucose meter	
	CONTOUR PLUS LINK blood glucose meter	
	CONTOUR PLUS LINK 2.4 blood glucose meter	

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Number	Device Name	Intended purpose per IFU
Annex II List B		
IVD 0309	CONTOUR NEXT blood glucose test strips	The test strips are intended for self-testing by persons with diabetes and by healthcare professionals to monitor glucose concentrations in the whole blood samples. The Contour tests strips may be used as an aid to monitor the effectiveness of an individual's personal blood glucose controls program. The tests strips are not intended for the diagnosis of or screening for diabetes mellitus.
	CONTOUR PLUS blood glucose test strips	
	CONTOUR blood glucose test strips	
	CONTOUR TS blood glucose strip	
	CONTOUR CARE blood glucose test strips	
	CONTOUR FIT blood glucose test strips	
IVD 0309	CONTOUR NEXT controls	The control solutions are aqueous glucose solutions intended for self-testing by persons with diabetes and by healthcare professionals as a quality control check.
	CONTOUR PLUS controls	
	CONTOUR controls	
	CONTOUR TS controls	

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Number	Device Name	Intended purpose per IFU
Non-Annex II self-tests		
IVD 0400	Ketostix Reagent strips	KETOSTIX Reagent Strips are intended for self-testing by persons with diabetes and for healthcare professionals to monitor for the presence and concentration of acetoacetic acid (Ketone). The KETOSTIX Strips are specific for testing for Ketone in urine. This substance when found in the urine provides information on carbohydrate and fat metabolism.
	Keto-Diastix Reagent strips	KETO-DIASTIX Reagent Strips are intended for self- testing by persons with diabetes and for healthcare professionals to monitor for the presence and concentration of glucose and ketone (acetoacetic acid) in urine. KETO-DIASTIX Strips are specific for testing for glucose and ketone in urine. the urine from persons with diabetes. When dipped in urine, these test areas on the KETO-DIASTIX Strip change color according to the amount of glucose and ketone in the urine. Use of KETO-DIASTIX Reagent Strips can alert patients and doctors to changes in patient condition for which adjustments in diet and/or medication may be needed.
	Diastix Reagent strips	DIASTIX Reagent Strips are intended for self-testing by persons with diabetes and by healthcare professionals to monitor the level of glucose in urine. The Reagent Strip is specific for glucose and can only be used to determine the amount of glucose in urine. The reagent test area on DIASTIX is ready to use upon removal from the bottle.

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