

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.

List of Products - See certificate

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

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Date: **2020-01-31**

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Number	Device Name	Intended purpose per IFU
Annex II List B products		
IVD0309	CONTOUR XT blood glucose meter	<p>The CONTOUR XT blood glucose monitoring system (meter, test strips and control solution) is intended for self-testing by persons with diabetes and by health care professionals to monitor glucose concentrations in fresh capillary whole blood drawn from the fingertip, arterial and venous whole blood or neonatal blood. It is 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/dL).</p> <p>It is intended for in vitro diagnostic use only.</p> <p>The CONTOUR XT blood glucose monitoring system may be used as an aid to monitor the effectiveness of an individual's personal blood glucose control program. The CONTOUR XT blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus.</p>

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Number	Device Name	Intended purpose per IFU
Annex II List B products		
	CONTOUR NEXT blood glucose meter	<p>The CONTOUR NEXT blood glucose monitoring system (meter, test strips and control solution) is intended for self-testing by persons with diabetes and by health care professionals to monitor glucose concentrations in venous whole blood, fresh capillary whole blood drawn from the fingertip or palm, arterial blood and neonatal blood.</p> <p>It is 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/dL).</p> <p>It is intended for In Vitro diagnostic use only.</p> <p>The CONTOUR NEXT blood glucose monitoring system may be used as an aid to monitor the effectiveness of an individual's personal blood glucose control program.</p> <p>The CONTOUR NEXT blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus.</p>

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Annex II List B products		
	CONTOUR NEXT (Connected) blood glucose meter	<p>The Contour Next (Connected) blood glucose monitoring system is intended to be used for the measurement of blood glucose in both insulin and noninsulin treated patients with diabetes as an aid for patients and their HCPs in monitoring the effectiveness of the patient's diabetes control. The Contour Next (Connected) blood glucose monitoring system is intended for self-testing by persons with diabetes and health care professionals in venous blood and in fresh capillary whole blood drawn from the fingertip or palm. The Contour Next (Connected) blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use).</p> <p>The Contour Next (Connected) blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing (palm) should be done only during steady state times (when glucose is not changing rapidly). The Contour Next test strips are for use with the Contour®Next (Connected) blood glucose meter to quantitatively measure glucose in venous blood and fresh capillary whole blood drawn from the fingertips or palm. The meter is for the quantitative measurement of glucose in whole blood from 0.6 mmol/L to 33.3 mmol/L (10mg/dL to 600 mg/dL).</p> <p>The system is intended for in vitro diagnostic use only.</p>

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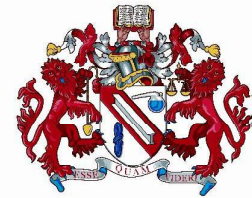
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Annex II List B products		
	CONTOUR NEXT LINK blood glucose meter	<p>The CONTOUR Next Link wireless blood glucose monitoring system (meter, test strips and control solution) is intended for self-testing by persons with diabetes to monitor glucose concentrations for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertip or palm. It is intended for in vitro diagnostic use only. The clinical utility of this device is that it may be used as an aid to monitor the effectiveness of a diabetes control program.</p> <p>The CONTOUR Next Link wireless blood glucose monitoring system is 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.</p> <p>The CONTOUR Next Link wireless blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus and it is not intended for use on neonates.</p>

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Annex II List B products		
	CONTOUR NEXT LINK 2.4 blood glucose meter	<p>The CONTOUR Next Link 2.4 wireless blood glucose monitoring system (meter, test strips and control solution) is 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. It is intended for in vitro diagnostic use only. The clinical utility of this device is that it may be used as an aid to monitor the effectiveness of a diabetes control program.</p> <p>The CONTOUR Next Link 2.4 wireless blood glucose monitoring system is intended to be used to transmit glucose values and send a remote bolus to Medtronic devices and facilitate transfer of information to Medtronic CareLink® Software through use of radio frequency communication.</p> <p>The CONTOUR Next Link 2.4 wireless blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus and it is not intended for use on neonates.</p>

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	CONTOUR NEXT ONE blood glucose meter	<p>The CONTOUR NEXT ONE blood glucose monitoring system is intended to be used for the measurement of blood glucose in both insulin and non-insulin treated patients with diabetes as an aid for patients and their HCPs in monitoring the effectiveness of the patient's diabetes control.</p> <p>The CONTOUR NEXT ONE blood glucose monitoring system is intended for self-testing by persons with diabetes and health care professionals in venous blood and in fresh capillary whole blood drawn from the fingertip or palm. The CONTOUR NEXT ONE blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use).</p> <p>The CONTOUR NEXT ONE blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing (palm) should be done only during steady state times (when glucose is not changing rapidly).</p> <p>The CONTOUR NEXT test strips are for use with the CONTOUR NEXT ONE blood glucose meter to quantitatively measure glucose in venous blood and fresh capillary whole blood drawn from the fingertips or palm.</p> <p>The meter is for the quantitative measurement of glucose in whole blood from 0.6 mmol/L–33.3 mmol/L (10mg/dL to 600 mg/dL).</p> <p>The system is intended for in vitro diagnostic use only.</p>

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	CONTOUR PLUS blood glucose meter	<p>The CONTOUR PLUS blood glucose monitoring system (meter, test strips and control solution) is intended for self-testing by persons with diabetes and by health care professionals to monitor glucose concentrations in fresh capillary whole blood drawn from the fingertip or palm, arterial and venous whole blood or neonatal blood.</p> <p>It is 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/dL).</p> <p>It is intended for in vitro diagnostic use only.</p> <p>The CONTOUR PLUS blood glucose monitoring system may be used as an aid to monitor the effectiveness of an individual's personal blood glucose control program.</p> <p>The CONTOUR PLUS blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus.</p>

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	CONTOUR PLUS LINK blood glucose meter	<p>The CONTOUR Plus Link wireless blood glucose monitoring system (meter, test strips and control solution) is 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. It is intended for in vitro diagnostic use only.</p> <p>The clinical utility of this device is that it may be used as an aid to monitor the effectiveness of a diabetes control program.</p> <p>The CONTOUR PLUS LINK wireless blood glucose monitoring system is 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.</p> <p>The CONTOUR PLUS LINK wireless blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus and it is not intended for use on neonates.</p>

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Annex II List B products		
	CONTOUR PLUS LINK 2.4 blood glucose meter	<p>The CONTOUR Plus Link 2.4 wireless blood glucose monitoring system from Ascensia (meter, test strips and control solution) is 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. It is intended for in vitro diagnostic use only. The clinical utility of this device is that it may be used as an aid to monitor the effectiveness of a diabetes control program.</p> <p>The CONTOUR Plus Link 2.4 wireless blood glucose monitoring system is intended to be used to transmit glucose values and send a remote bolus to Medtronic devices and facilitate transfer of information to Medtronic CareLink Software through use of radio frequency communication.</p> <p>The CONTOUR Plus Link 2.4 wireless blood glucose monitoring system from Ascensia is not intended for the diagnosis of or screening for diabetes mellitus and it is not intended for use on neonates.</p>

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	CONTOUR PLUS ONE blood glucose meter	<p>The CONTOUR PLUS ONE blood glucose monitoring system is intended to be used for the measurement of blood glucose in both insulin and non-insulin treated patients with diabetes as an aid for patients and their HCPs in monitoring the effectiveness of the patient's diabetes control.</p> <p>The CONTOUR PLUS ONE blood glucose monitoring system is intended for self-testing by persons with diabetes and health care professionals in venous blood and in fresh capillary whole blood drawn from the fingertip or palm. The CONTOUR PLUS ONE blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use).</p> <p>The CONTOUR PLUS ONE blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing (palm) should be done only during steady state times (when glucose is not changing rapidly).</p> <p>The CONTOUR PLUS test strips are for use with the CONTOUR PLUS ONE blood glucose meter to quantitatively measure glucose in venous blood and fresh capillary whole blood drawn from the fingertips or palm. The meter is for the quantitative measurement of glucose in whole blood from 0.6 mmol/L–33.3 mmol/L (10mg/dL to 600 mg/dL). The system is intended for in vitro diagnostic use only.</p>

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Annex II List B products		
	CONTOUR blood glucose meter	<p>The CONTOUR blood glucose monitoring system (meter, test strips and control solutions) is intended for self-testing by people with diabetes and by health care professionals to monitor glucose concentrations in fresh capillary whole blood drawn from the fingertip. In clinical settings, the CONTOUR system may also be used with fresh venous and arterial whole blood. It is intended for in vitro diagnostic use only.</p> <p>The test provides a quantitative measurement of glucose in blood from 10 mg/dL to 600 mg/dL (0.6 mmol/L to 33.3 mmol/L).</p> <p>The CONTOUR blood glucose monitoring system is not intended for diagnosis of or screening for diabetes mellitus and is not for use in neonatal care.</p>

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Number	Device Name	Intended purpose per IFU
Annex II List B products		
	CONTOUR TS blood glucose meter	<p>The CONTOUR TS blood glucose monitoring system (meter, test strips and control solutions) is intended for self-testing by people with diabetes and by health care professionals to monitor glucose concentrations in fresh capillary whole blood drawn from the fingertip.</p> <p>In clinical settings, the CONTOUR TS system may also be used with fresh venous and arterial whole blood.</p> <p>The test provides a quantitative measurement of glucose in blood from 10 mg/dL to 600 mg/dL (0.6 mmol/L to 33.3 mmol/L).</p> <p>The CONTOUR TS blood glucose monitoring system is not intended for diagnosis of or screening for diabetes mellitus and is not for use in neonatal care.</p> <p>It is intended for in vitro diagnostic use only.</p>

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Number	Device Name	Intended purpose per IFU
Annex II List B products		
	CONTOUR CARE blood glucose meter	<p>The Contour Care blood glucose monitoring system is intended to be used for the measurement of blood glucose in both insulin and non-insulin treated patients with diabetes as an aid for patients and their HCPs in monitoring the effectiveness of the patient's diabetes control. The Contour Care blood glucose monitoring system is intended for self-testing by persons with diabetes and health care professionals in venous blood and in fresh capillary whole blood drawn from the fingertip or palm. The Contour Care blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use). The Contour Care blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing (palm) should be done only during steady state times (when glucose is not changing rapidly). The Contour Care test strips are for use with the Contour Care blood glucose meter to quantitatively measure glucose in venous blood and fresh capillary whole blood drawn from the fingertips or palm. The meter is for the quantitative measurement of glucose in whole blood from 0.6 mmol/L to 33.3 mmol/L (10mg/dL to 600 mg/dL). The system is intended for in vitro diagnostic use only.</p>

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Annex II List B products		
	CONTOUR NEXT blood glucose test strips	The test strips are intended for self-testing by persons with diabetes and by health care professionals to monitor glucose concentrations in whole blood samples. The Contour test strips may be used as an aid to monitor the effectiveness of an individual's personal blood glucose control program. The Contour test 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 test strips	
	CONTOUR CARE Test Strips	

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Number	Device Name	Intended purpose per IFU
Annex II List B products		
	CONTOUR NEXT controls	The control solutions are aqueous glucose solutions intended for self-testing by persons with diabetes and by health care 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
Annex II List B products		
Self-tests		
IVD0400	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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