

## Declaration of Conformity

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### Declaration of Conformity

Manufacturer:	<b>SensCom AS</b> Ensjøveien 12D 0655 Oslo Norway						
EC Representative:	N/A						
Product(s):	<table border="1"> <thead> <tr> <th><u>Product</u></th> <th><u>Art.-No.</u></th> <th><u>Basic UDI-DI</u></th> </tr> </thead> <tbody> <tr> <td>DignaCare Sensor</td> <td>DC01</td> <td>709005332DC012A</td> </tr> </tbody> </table>	<u>Product</u>	<u>Art.-No.</u>	<u>Basic UDI-DI</u>	DignaCare Sensor	DC01	709005332DC012A
<u>Product</u>	<u>Art.-No.</u>	<u>Basic UDI-DI</u>					
DignaCare Sensor	DC01	709005332DC012A					
Intended use:	<i>The DignaCare Sensor is a flexible sensor strip that is attached to the outside of any incontinence product and notifies the need to change the product by a user-friendly application. The intended use of the DignaCare Sensor is to replace the physiological process of being able to detect urination or defecation for patients affected by incontinence. Incontinence is a pathological process where the ability to have voluntary control over urination and/or defecation is affected. When not able to treat the underlying mechanisms of incontinence, incontinence products are essential.</i>						
Conformity Assessment:	MDR, Regulation (EU) 2017/745, Art. 19 (Annex IV & V)						
Free Sales Cat. Number (GMDN)	11588 (Incontinence sensor/alarm)						
Classification:	Class I per Annex VIII of MDR Regulation (EU) 2017/745, acc. to Rule 1 and Rule 11. The device is long term use, non-invasive, and a software component on smartphones.						
We, the manufacturer, declares herewith under our sole responsibility that the above-mentioned product meets the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. All supporting documentation is retained on the premises of the manufacturer.							

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Place of Issue:	SensCom AS Ensjøveien 12D 0655 Oslo Norway
Signature / Title / Date	<p data-bbox="608 600 1433 667"><i>Ellen Cathrine Andersen</i></p> <p data-bbox="587 674 1378 712"><u>Ellen Cathrine Andersen (12. apr.. 2024 10:31 GMT+2)</u></p> <p data-bbox="595 725 1394 797">Ellen Catherine Andersen Chief Executive Officer <span style="float: right;">Date: 12. apr.. 2024</span></p> <p data-bbox="616 887 975 954"><i>Toan Tran</i></p> <p data-bbox="587 963 1185 1001"><u>Toan Tran (12. apr.. 2024 10:36 GMT+2)</u></p> <p data-bbox="595 1010 1385 1081">Toan Tran <span style="float: right;">Date: 12. apr.. 2024</span> Person Responsible for Regulatory Compliance</p>







# DHF 0019 - Rev 01 - Declaration of Conformity- Print version

Endelig revisjonsrapport

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Opprettet:	2024-04-12
Av:	Marius Fjeldet (marius@senscom.no)
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