

DECLARATION OF CONFORMITY

1 Manufacturer

SanoMed Manufacturing bv
 Address: Transportweg 13-001
 4501PS Oostburg
 The Netherlands

SRN: NL-MF-000002684

2 Product(s) (name, type or model):

- SanoSkin OXY 30 gram - Melladerm Plus 20 gram - Melladerm Plus 50 gram - Melloxy 20 gram - Melloxy 50 gram see appendix
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3 The product(s) described above is in conformity with:

<u>Title</u>	<u>Document No.</u>
Medical Device Regulation	(EU) 2017/745

4 Additional information (conformity procedure, Notified Body, CE certificate, etc.):

Conformity assessment procedure: Medical Device Regulation, **Annex IX without Chapter II**.
 Notified Body: KIWA NB-no: 0476 CE-certificate nr. : *MDR 00029-A (expiry 2029/05/05)*

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

Oostburg 2024/05/23

Jan Vandeputte, CEO



(Place & date of issue (yyyy-mm-dd))

(name; function and signature of manufacturer)

Appendix

Date: 2024- 05 - 24

List of devices

Product name	Trade name	Product code/ catalogue number/ unambiguous ref.	Intended purpose	Risk class/ rule ¹	Basic UDI-DI ²	UDI-DI	First date of CE- compliance
SanoSkin OXY	SanoSkin OXY 30 gram	OX30	Wound treatment	IIb rule 4	871775519OX4M	08717755190581	2008/07/30
Melladerm Plus	Melladerm Plus 20 gram	MDP20	Wound treatment	IIb rule 4	871775519MDPTK	08717755190604	2008/07/30
Melladerm Plus	Melladerm Plus 50 gram	MDP50	Wound treatment	IIb rule 4	871775519MDPTK	08717755190628	2008/07/30
Melloxy	Melloxy 20 gram	MO20	Wound treatment	IIb rule 4	871775519MO3V	08717755190642	2008/07/30
Melloxy	Melloxy 50 gram	MO50	Wound treatment	IIb rule 4	871775519MO3V	08717755190666	2008/07/30

¹ See risk classification in Medical Device Regulation, annex VIII

² Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI