

(T52) Declaration of Conformity

FRM-507867, V3.0

GSK Consumer Healthcare

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Replaces document: FRM-507867 (v2.0)

Relates to: SOP-208793

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Completed by Manufacturer:

Document No./Name: 18	Version Number: 18 (1223417)
Issue date: 20 AUG 2020	Valid to date: 20 AUG 2025
Name of Manufacturer:	GSK Consumer Healthcare (GMDT)
Address of Manufacturer:	GSK Consumer Healthcare (GMDT), Clocherane, Youghal Road, Dungarvan, Co. Waterford, Ireland
Name of Device:	Sensodyne Repair and Protect Sensodyne Repair and Protect Whitening Sensodyne Repair and Protect Extra Fresh Sensodyne Complete Protection Sensodyne Complete Protection Extra Fresh
Intended Use:	Occluding dentifrice for dentinal hypersensitivity
Device Classification:	Class II a
Notified Body and number:	SGS Belgium NV, SGS House Noorderlaan 87 2030 Antwerp Belgium Notified Body number: 1639
Product Lines and Formula Number:	<ul style="list-style-type: none">• MFC04500 (Sensodyne Repair and Protect, Sensodyne Complete Protection)• MFC 04569 (Sensodyne Repair and Protect Whitening)• MFC04502 (Sensodyne Repair and Protect Extra Fresh, Sensodyne Complete Protection Extra Fresh)• MFC05093 (Sensodyne Repair & Protect)• MFC05096 (Sensodyne Repair & Protect Extra Fresh)• MFC05098 (Sensodyne Repair & Protect Whitening)
Batch number:	All lots released from/All lots manufactured from Aug 2020 until such time as significant changes are made to product, its starting materials or key subcontractors.

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Address of Fabrication Site(s):	Formula Supplied from Fabrication Site:
GSK Consumer Healthcare Norreys Drive Maidenhead Berkshire, SL6 4BL United Kingdom	MFC04500, MFC04502, MFC04569
GSK Consumer Healthcare Levice, s.r.o Priemyselny park GEŇA, Ul. E. Sachsa 4-6 934 01 LEVICE Slovakia	MFC04500, MFC04502, MFC04569, MFC05093, MFC05096, MFC05098
Neocosmed Co., Ltd. 222 Moo 4, Ladlumkaew Pathamthani, 12140 Thailand	MFC04500, MFC04502, MFC04569

We, the undersigned, hereby declare that the medical device specified above conforms to the Essential Requirements listed in Annex I of Council Directive 93/42/EEC (as amended by directive 2007/47/EC)

The required technical documentation has been prepared and is available to the national authorities for inspection purposes.

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This declaration is supported by EC Quality Certificate Annex V No. GB20/965118 (Occluding dentifrice for dentinal hypersensitivity) issued by SGS Belgium NV, Notified Body No. 1639 and Quality System Approval Certificate GB19/963036.

	Management Representative/Legal Manufacturer	Regulatory Affairs, signing to confirm that the Essential Requirements are met.
Place	GMDT Ireland and UK	Weybridge, Surrey, UK
Date	19 th Aug 2020	20 Aug 2020
Signature	A Oakley	B Hedges
Full Name	Andrew Oakley	Ben Hedges
Position	Quality Systems Manager GSK Consumer Healthcare (GMDT)	Regulatory Affairs Director- Therapeutic Oral Care GSK Consumer Healthcare

(GSK staff to confirm any proposed registrations with named manufacturer)

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Template revision history

REVISION (Principal Changes from last revision)
Type of change: <input type="checkbox"/> New <input checked="" type="checkbox"/> Revision with minor changes; <input type="checkbox"/> Revision with major changes impacting: <input type="checkbox"/> Roles and responsibilities <input type="checkbox"/> process or activities
Reason for Change: 1,2 – NPI Ultranova Project – CC 1223405/ 1223417
Description of Change: 1. The following Ultranova formulations have been added to Product Lines and Formula number section: MFC05093 (Sensodyne Repair & Protect) MFC05096 (Sensodyne Repair & Protect Extra Fresh) MFC05098 (Sensodyne Repair & Protect Whitening) 2. Ultranova formulations added for Levice Fabrication Site