EU MDD Declaration of Conformity

Governing SOP: QD-SOP-009864 Compliance to MDD and IVDD and Route to CE Marking

EU MDD Declaration of Conformity

Completed by Manufacturer:

Identification of the Legal Manufacturer:	 GSK Consumer Healthcare (GMDT), Clocherane , Youghal Road , Dungarvan Co.Waterford , Ireland
This Declaration of Conformity is issued under the sole responsibility of the GSK Consumer Healthcare (GMDT).	
Identification of the device(s) concerned:	Product Description / Formulation: Sensodyne Rapid Relief — MFC04733, MFC05142 Sensodyne Rapid Relief Whitening — MFC04734, MFC05143 Sensodyne Rapid Relief Extra Fresh — MFC04735 Sensodyne Complete Care — MFC04325 Sensodyne Complete Care Extra Fresh — MFC04186 Sensodyne Sensitivity & Gum — MFC04992 Sensodyne Sensitivity & Gum whitening (extra fresh in ANZ) — MFC04993
Trade Names:	As above
Intended Purpose of Device:	A physical dentine tubule occluding agent
Device Classification :	Class IIa Rule 5
Applicable CE Certificate and associated Annex :	EC Quality Certificate Annex V No. GB20/965118 (Occluding dentifrice for dentinal hypersensitivity)

Approved

<table>
<tr><td>Notified Body Name and Number:</td><td>SGS Belgium NV,
SGS House Noorderlaan 87
2030 Antwerp
Belgium

Notified Body number: 1639</td></tr>
<tr><td>Batch Number:</td><td>All lots released from/All lots manufactured from Apr 2021 until such time as significant changes are made to product, its starting materials or key subcontractors.</td></tr>
<tr><td>Name and Address of Manufacturing Site and applicable formulations</td><td>
<table>
<tr><th>Manufacturing Site Name and Address</th><th>Formulations Manufactured</th></tr>
<tr><td>GSK Consumer Healthcare
Norreys Drive
Maidenhead
Berkshire, SL6 4BL
United Kingdom</td><td>MFC04733, MFC05142
MFC04734, MFC05143
MFC04735
MFC04325
MFC04186
MFC04992, MFC04993</td></tr>
<tr><td>Neocosmed Co, Ltd
222 Moo 4
Rahaeng
Ladlumkaew
Pathumrhani 12140
Thailand</td><td>MFC05142,
MFC04735</td></tr>
</table>
</td></tr>
</table>

We, the approvers, 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.

This declaration is carried under Annex VII of Directive 93/42/EEC (as amended by 2007/47/EC).

Approved

Template revision history

REVISION **(Principal Changes from last revision)**
Type of change: ☐ New ☒ Revision with minor changes; ☐ Revision with major changes impacting: ☐ Roles and responsibilities ☐ process or activities **Reason for Change**: Change control : 1336624 **Description of Change**: Addition of Neocosmed manufacturing site. Dofc 24 v 6.0 has been updated and it will become version 1 in Veeva.

Approved

DoC Stannous Fluoride Sensodyne
Document Approvals by Electronic Signature

Verdict: Approve	Ben Hedges bjh97963 (ben.j.hedges@gskch.com) Regulatory Approval 19-Apr-2021 09:18:04 GMT+0000

Verdict: Approve	Katarzyna Wolska kap78654 (katarzyna.a.wolska@gskch.com) Author Approval 19-Apr-2021 12:39:44 GMT+0000

Verdict: Approve	Tara Roche tsr15383 (Tara.S.Roche@gskch.com) Quality Assurance Approval 20-Apr-2021 10:57:39 GMT+0000

Approved