

### DYMACARE® ORAL CARE SYSTEMS (DYOC200 SERIES GROUP SPEC)

<b>PRODUCT REFERENCES:</b>	DYOC2XX
<b>PACK TYPE:</b>	Flow-wrapped oral care system.
<b>SPEC VERSION:</b>	3
<b>DATE:</b>	19 <sup>th</sup> July 2022



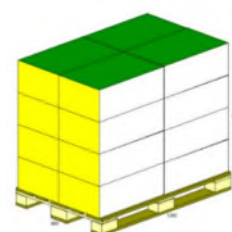
**PRODUCT DESCRIPTION:** Dymacare's Oral Care Systems (DYOC2XX) are designed to standardise & simplify the provision of oral care. Each system contains a pre-set combination of oral care components (any single component is part of the DYOC100 series, DYOC1XX). The individual components (DYOC1XX) that comprise each system are packaged onto a dental tray, and flow-wrapped to provide the user with a convenient single use pack (see overleaf).

**PRIMARY PACKAGING:** Dymacare Oral Care systems are packaged in disposable, single-use flow-wrapped packs. **Pack sizes:** (L)290 mm x (D)90mm x (H)30mm (nominal). To open wrapper, break heat sealed seams. Batch information is printed on each packet.

**DISPENSER CASING:** There are x50 flow-wrapped system packs per Dymacare dispenser. **Dispenser dimensions:** (L)587mm x (D)182mm x (H)269mm.

**TRANSIT CASING:** A transit case contains x2 Dymacare dispensers (100 system packs in total). Transit case dimensions: (L)600mm x (H)279mm x (D)379mm

**PALLETISATION:** EURO pallet (800mm x 1200mm, ~20kg)  
16 transit cases per pallet (4 per layer x 4 high)  
Packed pallet height: not more than 1375mm  
Packed pallet weight: not more than 130kg.  
A pallet contains 1,600 system packs



**TRANSPORT:** Classified as non-hazardous with commodity code: 9018499000

**ACCREDITATION:** Dymacare Oral Care Systems comprise the following product types:  
*Class IIa medical device, CE Marked & certified to EU Directive 93/42/EEC, non-sterile*  
*Class I medical device, CE Marked in accordance with EU Regulation 2017/745 MDR, Annex VIII, Rule 5. Non-sterile.*  
*Oral care formulations compliant with EU Cosmetic Reg. (EC) No 1223/2009 (as amended)*

**MANUFACTURING:** Manufactured in accordance with ISO13485:2016. Made in the UK

**COMPOSITION:** Dental Tray – 100% PET. For all other components, please see the individual DYOC100 series specifications.

**DENTAL TRAY (100% PET):** At the top of the dental tray is a compartment to hold the dispensed mouthwash, moisturising gel, or your own oral care formula. **Tray dimensions (approx.):** (L)23cm x (W)7.5cm x (H)2.2cm

**ORAL CARE SYSTEM COMPONENT(S):** Each System comprises a combinations of the following oral care components:

**DYOC100\*** - untreated suction toothbrush.

**DYOC101\*** - untreated suction swab.

**DYOC102\*** – untreated oral swab.

**DYOC103\*** – sodium bicarbonate treated suction swab.

**DYOC104\*** – sodium bicarbonate treated oral swab.

**DYOC105\*** – alcohol-free mouthwash.

**DYOC106\*** – mouth moisturiser.

**DYOC108** – dental dispenser tray.

(\*) Indicates that a unique DYOC1XX series specification is available upon request.

### DYOC200 SERIES SYSTEMS:

**DYOC201 - Dymacare® Untreated Oral Suction Toothbrush - System 1:** 1x untreated suction toothbrush, 1x untreated oral swab, 1x alcohol-free mouthwash (15ml), 1x mouth moisturiser (4g), 1x dental dispenser tray.

**DYOC202 - Dymacare® Sodium Bicarbonate Treated Oral Swab System:** 2x treated oral swabs, 1x alcohol-free mouthwash (15ml), 1x mouth moisturiser (4g).

**DYOC203 - Dymacare® Sodium Bicarbonate Treated Oral Suction Swab – System 1:** 2x treated suction swabs, 1x untreated oral swab, 1x dental dispenser tray.

**DYOC204 - Dymacare® Sodium Bicarbonate Treated Oral Suction Swab – System 2:** 2x treated suction swabs, 1x untreated oral swab, 1x alcohol-free mouthwash (15ml), 1x mouth moisturiser (4g), 1x dental dispenser tray.

**DYOC205 - Dymacare® Untreated Oral Suction Toothbrush - System 2:** 1x untreated suction toothbrush, 1x untreated oral swab, 1x dental dispenser tray.

**DYOC206 - Dymacare® Untreated Suction Toothbrush & Swab System:** 1x untreated suction toothbrush, 1x untreated suction oral swab, 1x dental dispenser tray.

**DYOC207 - Dymacare® Untreated Oral Swab System:** 2x untreated suction swabs, 1x alcohol-free mouthwash (15ml), 1x mouth moisturiser (4g), 1x dental dispenser tray.

**DYOC208 - Dymacare® Sodium Bicarbonate Treated Oral Suction Swab – System 3:** 1x treated suction swab, 1x untreated oral swab, 1x alcohol-free mouthwash (15ml), 1x mouth moisturiser (4g), 1x dental dispenser tray.

**DYOC209 - Dymacare® Untreated Oral Suction Toothbrush & Swab – System 2:** 1x untreated suction toothbrush, 1x untreated suction swab, 1x alcohol-free mouthwash (15ml), 1x mouth moisturiser (4g), 1x dental dispenser tray.