

**Medical Devices Directive 93/42/EEC, amendment 2007/47/EC and  
the relevant articles of the Medical Devices Regulation 2017/745**

**CLASS IIa MEDICAL DEVICES**

**DECLARATION OF CONFORMITY**

Prophy Cups

Medical Device	Basic UDI-DI	GMDN Code	EMDN Code
Prophy Polishers	5051717DP01TU	<b>46938</b> Dental Polishing Cup, single use	<b>Q010599</b> Dental Instruments, Single Use - other

**NBOG Codes**

<b>MDN Code</b>	<b>1208</b>	Non-active, non-implantable instruments
<b>MDT Code</b>	<b>2001</b>	Devices manufactured using metal processing
	<b>2002</b>	Devices manufactured using plastic processing
	<b>2011</b>	Devices which require packaging, including labelling
<b>MDS Code</b>	<b>N/A</b>	



Stoddard Manufacturing Company Limited, Blackhorse Road, Letchworth, Herts, SG6 1HB

**Manufacturer SRN (Single Registration Number):** GB-MF-000004681



**EU REP**

Stoddard ApS, Moellegade 32, 8000 Aarhus C, Denmark

**Importer SRN (Single Registration Number):** DK-IM-000006663

**EU Authorised Representative SRN (Single Registration Number):** DK-AR-000002857

**CH REP**

EUMEDIQ AG, Grafenauweg 8, CH-6300 Zug, Switzerland

**CH Authorised Representative SRN (Single Registration Number):** CHRN-AR-20001336

**Notified Body:** SGS Belgium NV, SGS House, Noorderlaan 87 - 2030, Antwerp, Belgium

**CE number:** 1639

**Certificate number:** GB19/964442

**Definition of a medical device:** A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose.

**Description:** Stoddard Prophy Cups are a latex free synthetic polymer moulded product.

**Intended use:** The devices are intended to be used by or under the instruction of a qualified dental professional on patients of any age for the prophy cleaning or polishing of natural teeth, gold and amalgam filled surfaces in the mouth to remove plaque and stains. Dental prophylaxis is a cleaning procedure performed to thoroughly clean the teeth. Prophylaxis is an important dental treatment for halting the progression of Periodontal disease and gingivitis. The devices are single use devices dental rotary instruments and are supplied mechanically clean but are not sterile and, therefore, should be sterilised before use.

All manufacturing activities are subject to appropriate systems of internal control and inspection as governed by the accredited BS EN ISO 13485 Quality Management System, Medical Devices Directive 93/42/EEC, amendment 2007/47/EC and in compliance with the relevant articles of the Medical Devices Regulation 2017/745.

The conformity of the medical devices is subject to the procedure set out in Annex V of the Medical Device Directive 93/42/EEC and amendment 2007/47/EC under the supervision and inspection of SGS Belgium NV, SGS House, Noorderlaan 87 - 2030, Antwerp, Belgium as identified by Notified Body number 1639.

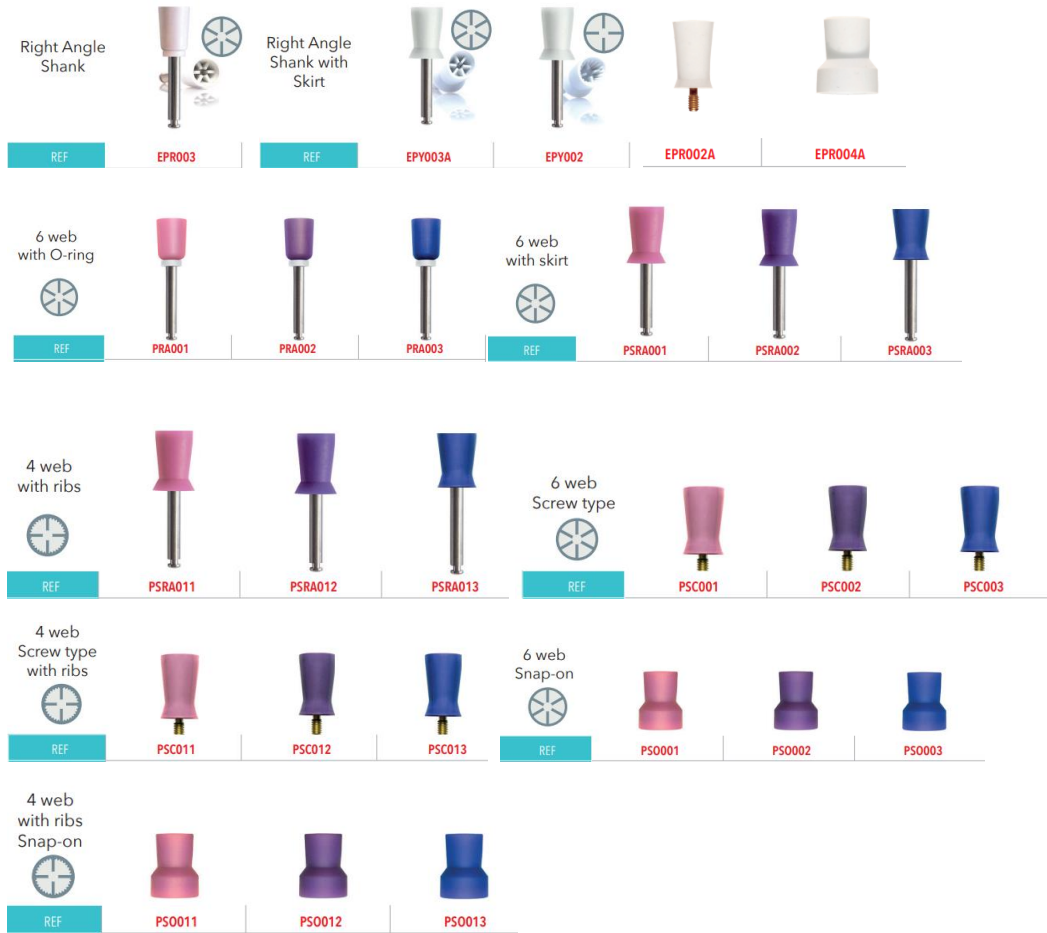
Stoddard Manufacturing Company Limited accept responsibility as the manufacturer and hereby declare that the devices as listed below, have been classified as Class IIa (MDD Annex IX rule 5 & MDR Annex VIII rule 5) and are in conformity with the General Safety and Performance Requirements of the Medical Device Regulation 2017/745

and

BS EN ISO 1797, BS EN ISO 10993-1, BS EN ISO 10993-12, BS EN ISO 14971, BS EN ISO 7405, BS 6001-1, BS EN 62366-1, BS EN ISO 15223-1, BS EN ISO 15223-2, BS EN 1041, BS EN ISO 17664, BS EN ISO 17665, BS EN ISO 14457, BS EN 1639, BS EN 1640, BS EN 15552 and BS EN ISO 14155.

PRA001	Prophy Cup, Pink, 6 Web, Ring, RA
PRA002	Prophy Cup, Purple, 6 Web, Ring, RA
PRA003	Prophy Cup, Blue, 6 Web, Ring, RA
PSRA001	Prophy Cup, Pink, 6 Web, RA
PSRA002	Prophy Cup, Purple, 6 Web, RA
PSRA003	Prophy Cup, Blue, 6 Web, RA
PSRA004	Prophy Cup, White, 6 Web, RA
PSRA005	Prophy Cup, Yellow, 6 Web, RA
PSRA011	Prophy Cup, Pink, 4 Web, Ribbed, RA
PSRA012	Prophy Cup, Purple, 4 Web, Ribbed, RA
PSRA013	Prophy Cup, Blue, 4 Web, Ribbed, RA
PSRA015	Prophy Cup, Yellow, 4 Web, RA
PSRA017	Prophy Cup, Green, 4 Web, RA
TPY002G	Prophy Cup, White, 4 Web, RA
EPR003	Prophy Cup, Mint, 6 Web Ring, RA
EPY002	Prophy Cup, Mint, 4 Web, Ribbed, RA
EPY003A	Prophy Cup, Mint, 6 Web, RA
PSC001	Prophy Cup, Pink, 6 Web, Screw
PSC002	Prophy Cup, Purple, 6 Web, Screw
PSC003	Prophy Cup, Blue, 6 Web, Screw
PSC004	Prophy Cup, White, 6 Web, Screw
PSC005	Prophy Cup, Yellow, 6 Web, Screw
PSC011	Prophy Cup, Pink, 4 Web, Ribbed, Screw
PSC012	Prophy Cup, Purple, 4 Web, Ribbed, Screw
PSC013	Prophy Cup, Blue, 4 Web, Ribbed, Screw
PSC014	Prophy Cup, Blue, 4 Web, Ribbed, Screw
PSC015XH	Prophy Cup, Yellow, 4 Web, Ribbed, Screw
PSC018	Prophy Cup, Green, 4 Web, Ribbed, Screw
PSC020	Prophy Cup, Green, 4 Web, Ribbed, Screw
EPR002A	Prophy Cup, White, 6 Web, Screw
PSO001	Prophy Cup, Pink, 6 Web, Snap-On
PSO002	Prophy Cup, Purple, 6 Web, Snap-On
PSO003	Prophy Cup, Blue, 6 Web, Snap-On
PSO004	Prophy Cup, White, 6 Web, Snap-On
PSO005	Prophy Cup, Yellow, 6 Web, Snap-On
PSO011	Prophy Cup, Pink, 4 Web, Ribbed, Snap-On
PSO012	Prophy Cup, Purple, 4 Web, Ribbed, Snap-On
PSO013	Prophy Cup, Blue, 4 Web, Ribbed, Snap-On
PSO015	Prophy Cup, Yellow, 4 Web, Ribbed, Snap-On
PSO019	Prophy Cup, Green, 4 Web, Ribbed, Snap-On
PSO020	Prophy Cup, Yellow, 4 Web, Ribbed, Snap-On
PSO021	Prophy Cup, Grey, 4 Web, Ribbed, Snap-On
PSO022	Prophy Cup, Green, 4 Web, Ribbed, Snap-On
PSO023	Prophy Cup, White, 4 Web, Ribbed, Snap-On
PSO028	Prophy Cup, Blue, 4 Web, Ribbed, Snap-On
EPR004A	Prophy Cup, White, 6 Web, Snap-On
PSMRA001	Prophy Cup Mini, Pink, 4 Web, Ribbed, RA
PSMRA002	Prophy Cup Mini, Purple, 4 Web, Ribbed, RA
PSMRA003	Prophy Cup Mini, Blue, 4 Web, Ribbed, RA
PSMSC001	Prophy Cup Mini, Pink, 4 Web, Ribbed, Screw
PSMSC002	Prophy Cup Mini, Purple, 4 Web, Ribbed, Screw

PSMSC003      Prophy Cup Mini, Blue, 4 Web, Ribbed, Screw  
 EPY004        Prophy Cup, Grey, Ribbed, RA  
 EPY005        Prophy Cup, Grey, Ribbed, Screw  
 TPR002A      Prophy Cup, White, 6 Web, Screw  
 TPR002H      Prophy Cup, Green, 4 Web Screw  
 TPR003        Prophy Cup, White, 6 Web, Ring, RA  
 TPY002        Prophy Cup, Mint, 4 Web, Ribbed, RA  
 TPY003A      Prophy Cup, White, 6 Web, RA



Signed on behalf of  
 Stoddard Manufacturing Company Limited  
 Letchworth

Jackie Brookes  
 Regulatory Officer

Date: 01 September 2025