

**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 Polishing Brushes

Medical Device	Basic UDI-DI	GMDN Code	EMDN Code
JC, Junior Cup Brushes KS, MT Brushes	5051717DP01TU	64015 Dental Professional Prophylaxis Brush, single use	Q010599 Dental Instruments, Single Use - other
JC, SIC & DIA Brushes KS, SIC & DIA Brushes	5051717DP01TU	35768 Dental Professional Prophylaxis Brush, reusable	Q010399 Dental Devices – other

NBOG Codes

MDN Code **1208** Non-active, non-implantable instruments

Nylon Brushes

MDT Code **2001** Devices manufactured using metal processing
2002 Devices manufactured using plastic processing
2011 Devices which require packaging, including labelling
MDS Code **N/A**

Bristle Brushes

MDT Code **2001** Devices manufactured using metal processing
2009 Devices manufactured using processing of materials of human, animal, or microbial origin
2011 Devices which require packaging, including labelling
MDS Code **1003** Devices manufactured utilising tissues or cells of animal origin for the bristle brushes

SiCa & Diamond Brushes

MDT Code **2001** Devices manufactured using metal processing
2011 Devices which require packaging, including labelling
MDS Code **1006** Re-usable surgical instruments



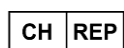
Stoddard Manufacturing Company Limited, Blackhorse Road, Letchworth, Herts, SG6 1HB
Manufacturer SRN (Single Registration Number): GB-MF-000004681



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 Brushes are filled in a variety of manmade and natural materials including white bristle, nylon, abrasive Silicon Carbide, abrasive Diamond filament.

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 majority of the devices are single use devices, however, the Diamond and SicA products are multi-use devices, and the instructions therefore apply before first and each subsequent use accordingly. The brushes are dental rotary instruments and are supplied mechanically clean but are not sterile and, therefore, should be sterilised before use.

Reusable devices and direct marking

Due to space constraints, the UDI information cannot be placed on the device itself, and is therefore, placed on the label on the primary packaging.

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.

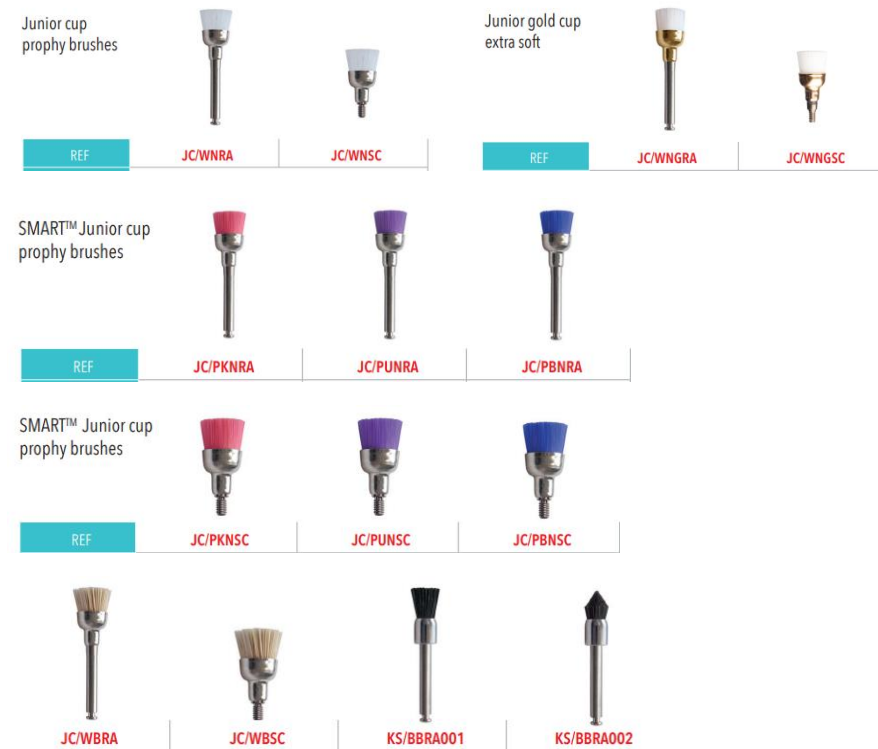
Stoddard Manufacturing Company Limited accept responsibility as the manufacturer and hereby declare that the devices as listed below, have been classified as Class IIa (MDD Annex IX rule 5 & MDR Annex VIII rule 5) and are in conformity with the General Safety and Performance Requirements of the Medical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

and

BS EN ISO 1797, BS EN ISO 10993-1, BS EN ISO 10993-5, 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 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.

Junior Cup Brushes

JC/WBRA	Junior Cup, White Bristle, RA
JC/WBSC	Junior Cup, White Bristle, Screw
JC/WNRA	Junior Cup, White Nylon, RA
JC/WNSC	Junior Cup White Nylon, Screw
JC/XWNRA	Junior Cup, Extra White Nylon, RA
JC/PKNRA	Junior Cup, Pink Nylon, RA
JC/PKNSC	Junior Cup, Pink Nylon, Screw
JC/PUNRA	Junior Cup, Purple Nylon, RA
JC/PUNSC	Junior Cup, Purple Nylon, Screw
JC/PBNRA	Junior Cup, Blue Nylon, RA
JC/PBNSC	Junior Cup, Blue Nylon, Screw
JC/SBNRA	Junior cup, Sky Blue Nylon, RA
JC/SBNSC	Junior Cup, Sky Blue Nylon, Screw
JC/GNRA	Junior Cup, Green Nylon, RA
JC/GNSC	Junior Cup, Green Nylon, Screw
JC/ORNRA	Junior Cup, Orange Nylon, RA
JC/YNRA	Junior Cup, Yellow Nylon, RA
JC/YNSC	Junior Cup, Yellow Nylon, Screw
JC/WNGRA	Junior Cup, White Nylon, Extra Soft (Gold Cup), RA
JC/WNGSC	Junior Cup, White Nylon, Extra Soft (Gold Cup), Screw



KS Pencil Brushes

KS/WBRA001	Pencil Brush, One Knot, White Bristle, RA
KS/WBRA002	Pencil Brush, One Knot White Bristle, Pointed, RA
KS/WBSC001	Pencil Brush, One Knot, White Bristle, Screw
KS/WBSC002	Pencil Brush, One Knot, White Bristle, Pointed, Screw
KS/WNRA001	Pencil Brush, One Knot, White Nylon, RA
KS/WNRA002	Pencil Brush, One Knot, White Nylon, Pointed, RA
KS/WNSC001	Pencil Brush, One Knot, White Nylon, Screw
KS/WNSC002	Pencil Brush, One Knot, White Nylon, Pointed, Screw
KS/PKNRA001	Pencil Brush, One Knot, Pink Nylon, RA
KS/PKNRA002	Pencil Brush, One Knot, Pink Nylon, Pointed, RA
KS/PUNRA001	Pencil Brush, One Knot, Purple Nylon, RA
KS/PUNRA002	Pencil Brush, One Knot, Purple Nylon, Pointed, RA
KS/PBNRA001	Pencil Brush, One Knot, Blue Nylon, RA
KS/PBNRA002	Pencil Brush, One Knot, Blue Nylon, Pointed, RA
KS/PKNSC001	Pencil Brush, One Knot, Pink Nylon, Screw
KS/PKNSC002	Pencil Brush, One Knot, Pink Nylon, Pointed, Screw
KS/PUNSC001	Pencil Brush, One Knot, Purple Nylon, Screw
KS/PUNSC002	Pencil Brush, One Knot, Purple Nylon, Pointed, Screw
KS/PBNSC001	Pencil Brush, One Knot, Blue Nylon, Screw
KS/PBNSC002	Pencil Brush, One Knot, Blue Nylon, Pointed, Screw
KS/ORNRA001	Pencil Brush, One Knot, Orange Nylon, RA
KS/ORNRA002	Pencil Brush, One Knot, Orange Nylon, Pointed, RA
KS/YNRA001	Pencil Brush, One Knot, Yellow Nylon, RA
KS/YNRA002	Pencil Brush, One Knot, Yellow Nylon, Pointed, RA
KS/YNSC001	Pencil Brush, One Knot, Yellow Nylon, Screw
KS/BBRA001	Pencil Brush, One Knot, Black Bristle, RA
KS/BBRA002	Pencil Brush, One Knot, Black Bristle, Pointed, RA
KS/BBSC001	Pencil Brush, One Knot, Black Bristle, Screw
KS/BBSC002	Pencil Brush, One Knot, Black Bristle, Pointed, Screw
KS/BNSC001	Pencil Brush, One Knot, Black Nylon, Flat trim, Screw

Pencil prophylaxis brushes



REF

KS/WNRA001

KS/WNSC001

KS/WNRA002

KS/WNSC002

SMART™ Pencil prophylaxis brushes



REF

KS/PKNRA001

KS/PUNRA001

KS/PBNRA001

KS/PKNRA002

KS/PUNRA002

KS/PBNRA002

Microtuft Brushes

MT/XWNRA	Microtuft, Extra White Nylon, RA
MT/XWNSC	Microtuft, Extra White Nylon, Screw
MT/PKNRA	Microtuft, Pink Nylon, RA
MT/PKNSC	Microtuft, Pink Nylon, Screw
MT/PUNRA	Microtuft, Purple Nylon, RA
MT/PUNSC	Microtuft, Purple Nylon, Screw
MT/PBNRA	Microtuft, Blue Nylon, RA
MT/PBNSC	Microtuft, Blue Nylon, Screw
MT/SBNRA	Microtuft, Sky Blue Nylon, RA
MT/SBNSC	Microtuft, Sky Blue Nylon, Screw
MT/GNRA	Microtuft, Green Nylon, RA
MT/GNSC	Microtuft, Green Nylon, Screw
MT/YNRA	Microtuft, Yellow Nylon, RA

SMART™ Microtuft
prophy brushes
(w. long shank)



Junior Cup Brushes

JC/DIA/A	Junior Cup, Dia Brush, Gold Cup, RA
JC/SICRA/B	Junior Cup, Silicon Carbide, RA
JC/SICRA/G	Junior Cup, Silicon Carbide, Gold Cup, RA

KS Pencil Brushes

KS/DIA/A/001	Dia Brush, Pencil, RA, Gold Cup
KS/DIA/A/002	Dia Brush, Pencil, Pointed, RA Gold Cup
KS/SICRA/C	Silicon Carbide, Pencil, RA
KS/SICRA/D	Silicon Carbide, Pencil, Pointed, RA
KS/SICRA/E	Silicon Carbide, Pencil, Gold Cup, RA
KS/SICRA/F	Silicon Carbide, Pencil, Pointed, Gold Cup, RA



Signed on behalf of
Stoddard Manufacturing Company Limited, Letchworth

Jackie Brookes
Regulatory Officer

Date: 01 September 2025