Instruction for Use Soprano® Surface

1 Scope of application of Instructions for Use

These Instructions for Use apply to the products listed under Point 29 in Table 1. The issuing of these Instructions for Use renders all previous versions invalid. The manufacturer rejects any liability for damages resulting from non-compliance with these Instructions for Use.

2 Trade name

See Point 29, Table 1.

3 Intended use

The components are intended for use for prosthetic restoration and to support procedures in the dental clinic or laboratory.

4 Expected clinical benefit

Restoration of chewing function and improvement of aesthetics.

5 Product description

Soprano® Surface is a ready-to-use, translucent, opalescent and fluorescent, paste-like glass-ceramic with pigments. It is used to structure and individualise zirconia, lithium disilicate and veneering ceramic restorations.

Classification according DIN EN ISO 6872; type 1, Class 1

6 Indications

Use on the following framework materials:

– Fully anatomically fabricated crowns and bridges in tetragonal stabilised zirconia (Y -TZP) with a thermal expansion of approx. $10.6 \cdot 10^{-6} \cdot K^{-1}$ (25 - 500 °C).
– Crowns and bridges in tetragonal stabilised zirconia (Y -TZP) with a thermal expansion of approx. $10.6 \cdot 10^{-6} \cdot K^{-1}$ (25 - 500 °C), veneered with a zirconia oxide ceramic, for example Soprano® 10.
– Monolithic lithium disilicate glass ceramic materials with a thermal expansion of approx. $10.0 \cdot 10^{-6} \cdot K^{-1}$ (25 - 500 °C), for example Livento® press.
– Lithium disilicate glass ceramic materials with a thermal expansion of approx. $10.0 \cdot 10^{-6} \cdot K^{-1}$ (25 - 500 °C), for example Livento® press, veneered with Soprano® 10.
– PFM restorations, for example veneered with Soprano® 14

7 Contraindications

– Veneering of non-indexed framework materials
– Mixing with other ceramics (powders, pastes)
– Inlaying with other ceramics (powders, pastes)
– Use of other liquids
– Lacking compliance of the patient with respect to follow-up / recall instructions.
– Patients with bruxism or other para-functional habits.
– In patients with allergies to one or more elements of the materials used in the product.
– Existing clinical picture in the patient's mouth does not permit the correct application of the products.

8 Compatible products

Not applicable.

9 User qualification

The expertise of a professional dentist or dental technician is required. The current Instructions for Use must be available at all times and be completely read and understood before the first application. The manufacturing work and its maintenance must be carried out by qualified specialists.

Important information for the specialist

⚠ Warning symbol for increased caution

10 Prescription

Federal laws (USA) prohibit the use or sale by unlicensed dentists.

11 Side effects

⚠ This product may not be used in patients with allergies to one or more elements of the product materials. In patients with suspected allergy to one or more elements of the materials, this product may only be used following allergological clarification and proof of non-existence of an allergy.
Auxiliary instruments and products made of steel may contain nickel.
No known side effects if used as intended.

12 Warnings

⚠ **Magnetic resonance environment**
The device has not been evaluated for safety and compatibility in the MR environment.
The product has not been tested for heating or migration in the MR environment.

13 General information

These Instructions for Use are sufficient for immediate application for the products described in this application area of the instructions for Use. Dental or laboratory knowledge is required. Information: www.cmsa.ch/docs

14 Preventive measures

– The mechanical cleaning with a toothbrush and toothpaste may lead to premature wear.
– When grinding, wear protective goggles and a dust mask and use a suction unit.

– Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.
– The product components are supplied non-sterile. For more information see Point 16 Preparation.
– Secure parts against aspiration.
– Before any procedure, ensure that all required product components are available in sufficient quantity.
– For your safety, always wear suitable protective clothing.

15 Single use

Unless labelled otherwise, the product components are only intended for single use. Products that are marked for single-use are subject to a certain load during their use, which can lead to wear, loss of function and/or malfunctions.

⚠ Reuse of products marked as single-use products may compromise safety, function and performance.
Products for single-use have not been tested for reuse/reprocessing, which increases the risk of infection transmission.

16 Preparation

After any fabrication or modification and prior to use, the prosthetic work, including all system components, must be cleaned, disinfected and, if appropriate, sterilised. Materials made of metal alloys, high-performance polymers (Pekkton®) and ceramics are suitable for steam sterilisation, whereas components made of plastic other than Pekkton® are not suitable. Consider published national guidelines when selecting a disinfection and sterilisation process and the Instructions for Use "Reprocessing of surgical and prosthetic products" (www.cmsa.ch/docs).

17 Scope of application

The Soprano® Surface ceramic is processed in the dental laboratory with already well known, established dental ceramic instruments, processing instruments, mixing plates, furnaces and associated accessories.
This means that no new, product-specific accessories are required for the use of Soprano® Surface.

18 Procedure

18.1 Description of the ceramic colours and pastes:

Flu-Shade; body shade for the colouring of the A, B, C and D colours.

Flu-Stain; effect stains for individual, characteristic colouring.

Surface Base, Mamelon, Fossa and Cuspid; placement of individual characteristics.

Surface Enamel Effect; highlight of individual transpaeffects in the incisal area.

Surface Enamel V; neutral masses with stepped brightness for placing individual features and brightening the tooth shade. V1 has the highest brightness, V3 the lowest brightness.

Surface Enamel Opal, Incisal and Clear; use in the incisal area.

Surface Gingiva; Harmonised pastes and stains for the natural appearance of the gingiva.

18.2 Notes on the ceramic pastes

– Soprano® Surface and Soprano® Stain & Shade pastes should not get in contact with water.
– Always use dry brushes or spatula.
– Mix Soprano® Surface and Soprano® Stain & Shade pastes before any usage with metal-free spatula.
– To adjust the desired consistency of the Soprano® Surface pastes, use only Soprano® Surface Fluid.
– To adjust the desired consistency of the Soprano® Stain & Shade pastes, use only Soprano® Glaze Fluid.
– Moisten brush with Soprano® Surface Fluid, respective Soprano® Glaze Fluid, before application of pastes.

18.3 Framework processing

– Preparation of the frameworks according to the manufacturer's instructions of the framework material.
– Avoid sharp edges and corners at all costs.
– Prepare the surface before application of Soprano® Surface and Soprano® Stain & Shade pastes by careful sandblasting with aluminium oxide (110 µm with 2 bar pressure).
– Before each application, clean the surface well with a steam jet and then dry.

18.4 Structuration

Layer thickness for Soprano® Surface per firing from 0.1 to max. 0.3 mm.

Before the first application of Soprano® Surface pastes, wet the surface with Soprano® Surface Fluid.

18.5 Colouration

Before the first application of Soprano® Stain & Shade pastes, wet the surface with Soprano® Glaze Fluid.

18.6 Glaze paste application

After grinding the surface, apply Soprano® Glaze Fluid thinly and evenly over the entire restoration.

18.7 Finishing

The level of brilliance can still be individually adjusted after glaze firing using polishing instruments and diamond polishing pastes.

18.8 Firing tables

Firing chart for Soprano® Surface and Soprano® Stain & Glaze pastes

For lithium disilicate (Livento® press) monolithic or veneered.
Veneering ceramic for zirconia oxide (Soprano® 10).

Starting temperature	Pre-drying	Closing time	Temparature rise	Start vacuum	End vacuum	Firing temperature	Holding time
°C	min	min	K/min	°C	°C	°C	min
400	3	4	45	670	720	720	2

Firing chart for Soprano® Surface and Soprano® Stain & Glaze pastes

For monolithic zirconia.
Metal-ceramic (Soprano® 14).

Starting temperature	Pre-drying	Closing time	Temparature rise	Start vacuum	End vacuum	Firing temperature	Holding time
°C	min	min	K/min	°C	°C	°C	min
400	3	4	45	670	770	770	1

For voluminous zirconia work > 3g, long-term cooling is required according to the manufacturer's instructions.

For voluminous restorations, open the furnace with an opening time of 2 minutes!

In case of multiple firings, the final temperature may be reduced by 10-20 °C, depending on the desired degree of gloss!

The firing temperatures given are reference values and may vary depending on the type of furnace used and the age of the device.

19 Materials

All Soprano® Surface and Soprano® Stain & Shade pastes comply to all applicable standards for dental ceramics (DIN EN ISO 6872, ISO 10993). All limits are undercut and thresholds are outperformed.

19.1 Soprano® Surface

Physical-chemical properties according to ISO EN DIN 6872/ ISO 10993-5

Property	Specification	Measured data
Coefficient of thermal expansion (25 – 475°C) [× 10^{-6} × K^{-1} ± 0.5]	2 x: 9.5 4 x: 9.5	2 x: 9.5 4 x: 9.5
Glass transformation temperature Tg [°C ± 20]	2 x: 495 4 x: 495	2 x: 495 4 x: 495
Bending strength [MPa]	≥ 50	130 – 150
Solubility [µg/cm^2]	< 100	19 – 35
Radioactivity [Bq•g^{-1} U^{238}]	< 1	Complies*
Cytotoxicity	no cytotoxicity	Complies**

*) covered by report 170231-20-A, 17-02-01, mds, D-Gilching
**) covered by analysis report 17-10238, 17-01-20, FZ Jülich, D-Jülich

19.2 Soprano® Shade and Stain

Physical-chemical properties according to ISO EN DIN 6872/ ISO 10993-5

Property	Specification	Measured data
Coefficient of thermal expansion (25 – 475°C) [× 10^{-6} × K^{-1} ± 0.5]	2 x: 10.0 4 x: 10.0	2 x: 9.8* 4 x: 9.8*
Glass transformation temperature Tg [°C ± 20]	2 x: 460 4 x: 460	2 x: 455* 4 x: 455*
Bending strength [MPa]	≥ 50	> 130*
Solubility [µg/cm^2]	< 100	Complies*
Radioactivity [Bq•g^{-1} U^{238}]	< 1	Complies**
Cytotoxicity	no cytotoxicity	Complies***

*) data for base material
**) covered by analysis report 17-10237, 17-01-20, FZ Jülich, D-Jülich
***) covered by report 170231-20-C, 17-02-01, mds, D-Gilching

Detailed information on the materials and their classification is given in the specific material data sheets, the catalogue as well as the product list given in Table 1 in Point 29. See website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).

20 Notes on storage

The product must be stored in a dry place in its original packaging, at room temperature and without direct sunlight, unless otherwise stated on the packaging. Improper storage can influence the product properties and lead to failure of the restoration.

21 Patient information

21.1 Handling / follow-up

On the day of insertion of the dentures at the latest, the patient must be informed that regular follow-up care is necessary to maintain the health of the entire masticatory system and the functionality of the denture. Ensure that patients are motivated and instructed according to their own abilities such as manual dexterity and vision with regard to the handling and care of their teeth and dentures.

Permanent and removable dentures are subject to considerable stress in the mouth in a constantly changing environment, and thus more or less subjected to signs of wear. Wear is omnipresent in daily routine and cannot be avoided, only reduced. The amount of wear depends on the overall system.

Our endeavours are aimed at using materials that are as optimally matched as possible in order to reduce wear to an absolute minimum. Proper seating of the dentures on the mucosa must be checked at least once each year, and relining must be performed if required to prevent rocking movement (overload). We recommend checking the dentures at intervals of approx. 3 months initially and to replace the auxiliary parts such as retention inserts if necessary.

21.2 Cleaning and care

We recommend cleaning your teeth and your dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. The gentlest cleaning is achieved by cleaning the connecting element under running water with a soft toothbrush. The most intensive cleaning is achieved when cleaning the dentures in a small ultrasonic device and adding a suitable cleaning agent. Never clean the high precision connecting elements with toothpaste. This could lead to damage. Caution should also be exercised in the case of unsuitable cleaning agents or tablets. This could also damage the high quality connecting element or impair its function. Only clean the connecting parts on the other teeth or implants with water and a soft toothbrush as well as an interdental brush. Do not use toothpaste to avoid damage.

Pay attention to regular cleaning of the anchorage to prevent any inflammation of the soft tissue.

For information and additional tips on caring for the instruments see the website (www.cmsa.ch/docs).

For information and additional details, please contact your Cendres+Métaux SA representative.

22 Ordering information

More detailed information on the catalogue numbers, the number of products and their classification can be found in the product list under Point 29 in Table 1, the specific product catalogue, the packaging and, in the case of individual products, also directly on the product itself. You can find further information on the website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).
For information and additional details, please contact your Cendres+Métaux SA representative.

23 Availability

Some of the products described in this document may possibly not be available in all countries.

24 Traceability batch number

The batch numbers of all parts used must be documented to ensure traceability. If different batch numbers are used for the products described in this application area of the instructions for Use for the fabrication of dentures, all the batch numbers concerned must be recorded to ensure traceability.

25 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product to all branches, offices and dealers of Cendres+Métaux SA and, in case of serious cases, to the competent authority where the user is registered.

26 Safe disposal

The product must be disposed of in accordance with local laws and environmental regulations, taking into account the level of contamination. Cendres+Métaux LUX SA would be very pleased to accept precious metal waste. For information and additional details, please contact your Cendres+Métaux SA representative.

27 Trademarks

Registered trademarks of Cendres+Métaux Holding SA, Biel/Bienne, Switzerland include:

Soprano®

Unless explained specifically, all products marked with "®" are not registered trademarks of Cendres+Métaux Holding SA, but registered trademarks of the respective manufacturer.

28 Disclaimer

The manufacturer rejects any liability for damages resulting from non-compliance with these instructions for Use. This product is part of an overall concept and may only be used or combined with the corresponding original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the batch number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products listed in Table 1 will void any warranty or other express or implied obligations of Cendres+Métaux SA.

The user of Cendres+Métaux SA products is responsible for determining whether or not a product is suitable for a specific patient and a specific situation.

Cendres+Métaux SA disclaims any express or implied liability and shall not be responsible for any direct, indirect, punitive or other damages arising from or in connection with errors in professional judgement or practice in the use or installation of Cendres+Métaux SA products.

The user is also obliged to regularly study the latest developments of the Cendres+Métaux SA products listed in Table 1 and their applications.

Please note: the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products. Specialist knowledge of dentistry, dental technology and instructions in handling the products listed in Table 1 by an operator with appropriate experience is always required.

29 Product list

All Soprano® products are assigned the basic UDI-DI: 764016651000038E8 and all Livento® and Soprano® kits are assigned the number 764016651000039EA.

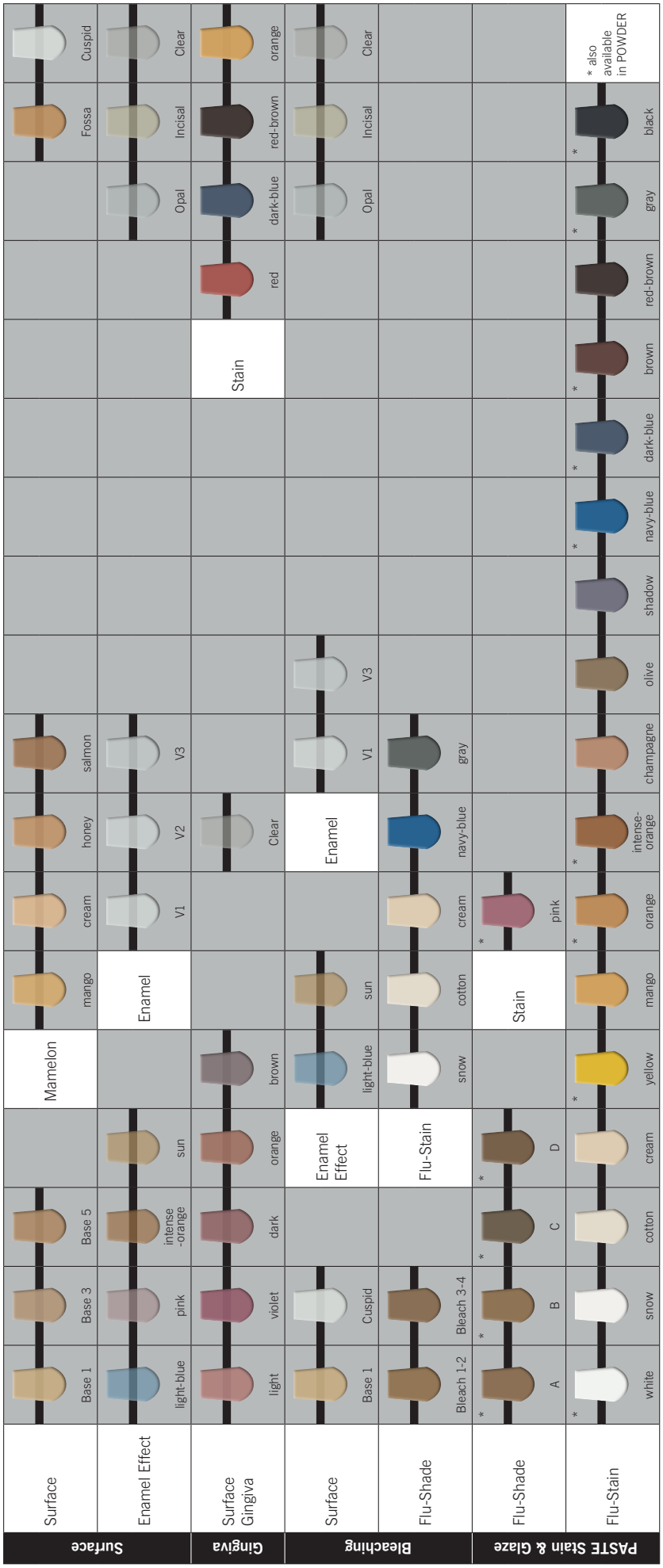
The Cat. No. and the UDI-Di Code of the single products corresponds to the refill article.

Product overview

Cat. No.	Product name	Kit contents	UDI-DI
08058206	**Soprano® Surface Kit**	**1**	**07640239930186**
08058207	Soprano® Surface Base 1	4 g	07640239930193
08058208	Soprano® Surface Base 3	4 g	07640239930209
08058209	Soprano® Surface Base 5	4 g	07640239930216
08058210	Soprano® Surface Mamelon mango	4 g	07640239930223
08058211	Soprano® Surface Mamelon cream	4 g	07640239930230
08058212	Soprano® Surface Mamelon honey	4 g	07640239930247
08058213	Soprano® Surface Mamelon salmon	4 g	07640239930254
08058214	Soprano® Surface Fossa	4 g	07640239930261
08058215	Soprano® Surface Cuspid	4 g	07640239930278
08058216	Soprano® Surface Enamel Effect light-blue	4 g	07640239930285
08058217	Soprano® Surface Enamel Effect pink	4 g	07640239930292
08058218	Soprano® Surface Enamel Effect int.-orange	4 g	07640239930308
08058219	Soprano® Surface Enamel Effect sun	4 g	07640239930315
08058220	Soprano® Surface Enamel V1	4 g	07640239930322
08058221	Soprano® Surface Enamel V2	4 g	07640239930339
08058222	Soprano® Surface Enamel V3	4 g	07640239930346
08058223	Soprano® Surface Opal	4 g	07640239930353
08058224	Soprano® Surface Incisal	4 g	07640239930360
08058225	Soprano® Surface Clear	4 g	07640239930377
08058226	Soprano® Surface Fluid	25 ml	07640239930384
08058227	**Soprano® Surface Gingiva Kit**	**1**	**07640239930391**
08058228	Soprano® Surface Gingiva light	4 g	07640239930407
08058229	Soprano® Surface Gingiva violet	4 g	07640239930414
08058230	Soprano® Surface Gingiva dark	4 g	07640239930421
08058231	Soprano® Surface Gingiva orange	4 g	07640239930438
08058232	Soprano® Surface Gingiva brown	4 g	07640239930445
08058225	Soprano® Surface Clear	4 g	07640239930377
08058226	Soprano® Surface Fluid	25 ml	07640239930384
08058233	Soprano® Stain red	5 g	07640239930452
08058234	Soprano® Stain dark-blue	5 g	07640239930469
08058235	Soprano® Stain red-brown	5 g	07640239930476
08058236	Soprano® Stain orange	5 g	07640239930483
08055184	Soprano® Glaze Paste	5 g	07640173094173
08055283	Soprano® Glaze Fluid	25 ml	07640173095729
08058237	**Soprano® Surface Bleaching Kit**	**1**	**07640239930490**
08058207	Soprano® Surface Base 1	4 g	07640239930193
08058215	Soprano® Surface Cuspid	4 g	07640239930278
08058216	Soprano® Surface Enamel Effect light-blue	4 g	07640239930285
08058219	Soprano® Surface Enamel Effect sun	4 g	07640239930315
08058220	Soprano® Surface Enamel V1	4 g	07640239930322
08058222	Soprano® Surface Enamel V3	4 g	07640239930346
08058223	Soprano® Surface Opal	4 g	07640239930353
08058224	Soprano® Surface Incisal	4 g	07640239930360
08058225	Soprano® Surface Clear	4 g	07640239930377
08058226	Soprano® Surface Fluid	25 ml	07640239930384
08058238	Soprano® Flu-Shade Bleach 1 - 2	5 g	07640239930506
08058239	Soprano® Flu-Shade Bleach 3 - 4	5 g	07640239930513
08058241	Soprano® Flu-Stain snow	5 g	07640239930100
08058242	Soprano® Flu-Stain cotton	5 g	07640239930117
08058243	Soprano® Flu-Stain cream	5 g	07640239930124
08055252	Soprano® Flu-Stain navy-blue	5 g	07640173095125
08055254	Soprano® Flu-Stain gray	5 g	07640173095149
08055184	Soprano® Glaze Paste	5 g	07640173094173
08055283	Soprano® Glace Fluid	25 ml	07640173095729

Cat. No.	Product name	Kit contents	UDI-DI
08058240	**Soprano® PASTE Stain&Glaze Universal Kit**	**1**	**07640239930094**
08055181	Soprano® Flu-Shade A	5 g	07640173094142
08055245	Soprano® Flu-Shade B	5 g	07640173095057
08055246	Soprano® Flu-Shade C	5 g	07640173095064
08055247	Soprano® Flu-Shade D	5 g	07640173095071
08055248	Soprano® Flu-Stain white	5 g	07640173095088
08058241	Soprano® Flu-Stain snow	5 g	07640239930100
08058242	Soprano® Flu-Stain cotton	5 g	07640239930117
08058243	Soprano® Flu-Stain cream	5 g	07640239930124
08055249	Soprano® Flu-Stain yellow	5 g	07640173095095
08058244	Soprano® Flu-Stain mango	5 g	07640239930131
08055250	Soprano® Flu-Stain orange	5 g	07640173095101
08055251	Soprano® Flu-Stain intense-orange	5 g	07640173095118
08058245	Soprano® Flu-Stain champagne	5 g	07640239930148
08058246	Soprano® Flu-Stain olive	5 g	07640239930155
08055255	Soprano® Stain pink	5 g	07640173095156
08058247	Soprano® Flu-Stain shadow	5 g	07640239930162
08055252	Soprano® Flu-Stain navy-blue	5 g	07640173095125
08055182	Soprano® Flu-Stain dark-blue	5 g	07640173094159
08055183	Soprano® Flu-Stain brown	5 g	07640173094166
08058248	Soprano® Flu-Stain red-brown	5 g	07640239930179
08055254	Soprano® Flu-Stain gray	5 g	07640173095149
08055253	Soprano® Flu-Stain black	5 g	07640173095132
08055184	Soprano® Glaze Paste	5 g	07640173094173
08055283	Soprano® Glaze Fluid	25 ml	07640173095729

Color Chart Soprano® Surface



30 Symbols

	Important information for the specialist
	Warning symbol for increased caution

Labelling on packaging / symbols

	Date of manufacture
	Manufacturer
REF	Catalogue number
LOT	Batch code
QTY	Quantity
 www.cmsa.ch/docs	Observe the Instructions for Use, which are available in electronic form at the address specified.
Rx only	Attention: According to US federal law, this product may only be sold by or on behalf of a physician.
CE 0483 CE	Cendres+Métaux products with CE labelling meet the requirements of the relevant European requirements.
	Do not re-use
	Non-sterile
	Keep away from sunlight
	Attention, observe accompanying documents
UDI 	Unique Device Identification – UDI
EC REP	European Authorised Representative
	Importer in EU
MD	Medical device

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