Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 045226 0007 Rev. 01

Manufacturer:	**White Smile GmbH** Weinheimer Str. 6 69488 Birkenau GERMANY
Facility(ies):	White Smile GmbH Weinheimer Str. 6, 69488 Birkenau, GERMANY
Product Category(ies):	**Tooth Whitening Gel / Bleaching Gel for professional use**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: 713160838

Valid from: 2019-10-22
Valid until: 2024-05-26

Date, 2019-10-22

Stefan Preiß
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

WHITEsmile GmbH
Weinheimer Straße 6
69488 Birkenau
Germany

Fon: +49 (0) 62 01/8 43 21-90
Fax: +49 (0) 62 01/8 43 21-99
info@whitesmile.de
www.whitesmile.de

Self-Declaration of compliance towards transitional provisions under Regulation (EU) 2023/607 amending Regulation (EU) 2017/745

This Self Declaration is issued under the sole responsibility of WHITEsmile GmbH, SRN DE-MF-000018734 and declares that the devices listed below are in conformity with the Regulation (EU) 2023/607 amending Regulations (EU) 2017/745, on medical devices.

Notified body name	TÜV SÜD Product Service GmbH
Notified body number	0123
Directive Certificate number to which this confirmation is made	G2 045226 0007 Rev. 01
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2024-05-26
End date of extended validity/transition period	2028-12-31

We, as the manufacturer declare under our sole responsibility:

1) The listed devices continue to comply with Directive 93/42/EEC.
2) There are no significant changes in the design and intended purpose devices listed below.
3) The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
4) Directive Certificate covering the listed devices was valid on 26 May 2021 and has not been suspended nor withdrawn. The certificate expires after May 26, 2021 (26.05.2024).
5) Before the date of expiry of the certificate, the manufacturer and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII to this Regulation for the conformity assessment.
6) A Quality Management System in accordance with Article 10(9) MDR is in place.
7) Requirements of Regulation (EU) 2017/745 relating to post-market surveillance, market surveillance and vigilance are met.

Signed for and on behalf of the manufacturer:

Birkenau, 22.05.2024
Place, Date

Benno Walter, CEO and PRRC WHITEsmile GmbH
info@whitesmile.com

WHITEsmile GmbH
Weinheimer Straße 6 · 69488 Birkenau · Germany
Fon +49(0)6201/84321-90 · Fax +49(0)6201/84321-99
info@whitesmile.de · www.whitesmile.de

Geschäftsführer/Managing Director:
Benno Walter, Jörg Haist
Amtsgericht Darmstadt | HRB 41387

Deutsche Bank Weinheim
BLZ 670 700 24
Konto 4 115 267

BIC DEUTDEDB670
IBAN DE41 6707 0024 0411 5267 00
USt-IdNr. DE814206124

VDDI Dental Solutions. German Manufacturers.

WHITEsmile GmbH
Weinheimer Straße 6
69488 Birkenau
Germany

Fon: +49 (0) 62 01/8 43 21-90
Fax: +49 (0) 62 01/8 43 21-99
info@whitesmile.de
www.whitesmile.de

The above Manufacturer's Declaration is valid for the following devices:

Device name	Device MDD REF numbers	MDD certificate reference	Notified Body name and number where the MDR application contract was signed
WHITEsmile LIGHT WHITENING AC 32% HP (mixed)	6602, 6612, 6622, 6662, 6702, 6712, 6812, 6832	G2 045226 0007 Rev. 01 Exp. Date: 2024-05-26 TÜV SÜD Product Service GmbH, 0123	TÜV SÜD Product Service GmbH, 0123
WHITEsmile POWER WHITENING YF 40% (mixed 32% HP)	5511, 5611, 5621, 5661, 5691, 5701, 5711, 5715, 5721, 5811, 5821, 5831, 5921, 5941	G2 045226 0007 Rev. 01 Exp. Date: 2024-05-26 TÜV SÜD Product Service GmbH, 0123	TÜV SÜD Product Service GmbH, 0123
WHITEsmile POWER WHITENING XTRA 38% (mixed 30% HP)	[redacted], 5696, [redacted], [redacted]	G2 045226 0007 Rev. 01 Exp. Date: 2024-05-26 TÜV SÜD Product Service GmbH, 0123	TÜV SÜD Product Service GmbH, 0123
WHITEsmile Gingiva Protector	5010, 5011	Not applicable, upclassified device under MDR	TÜV SÜD Product Service GmbH, 0123

WHITEsmile GmbH
Weinheimer Straße 6 · 69488 Birkenau · Germany
Fon +49(0)6201/84321-90 · Fax +49(0)6201/84321-99
info@whitesmile.de · www.whitesmile.de

WHITEsmile GmbH
Weinheimer Straße 6
69488 Birkenau
Germany

Fon: +49 (0) 62 01/8 43 21-90
Fax: +49 (0) 62 01/8 43 21-99
info@whitesmile.de
www.whitesmile.de

The above Manufacturer's Declaration is valid for the following devices:

Device name	Device MDD REF numbers	MDD certificate reference	Notified Body name and number where the MDR application contract was signed
WHITEsmile fläsh Light Whitening 32% HP (mixed)	3100, 3102, 3103, 3104, 3106	G2 045226 0007 Rev. 01 Exp. Date: 2024-05-26 TÜV SÜD Product Service GmbH, 0123	TÜV SÜD Product Service GmbH, 0123
WHITEsmile fläsh just 38% (mixed 30% HP)	3500, 3501	G2 045226 0007 Rev. 01 Exp. Date: 2024-05-26 TÜV SÜD Product Service GmbH, 0123	TÜV SÜD Product Service GmbH, 0123
WHITEsmile fläsh Gingiva Protector	3480	Not applicable, upclassified device under MDR	TÜV SÜD Product Service GmbH, 0123

WHITEsmile GmbH
Weinheimer Straße 6 · 69488 Birkenau · Germany
Fon +49(0)6201/84321 90 · Fax +49(0)6201/84321-99
info@whitesmile.de · www.whitesmile.de

Mehr Wert.
Mehr Vertrauen.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 München · Deutschland

WHITEsmile GmbH
Weinheimer Str. 6
69488 Birkenau

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
045226	713280314	medical devices@tuvsud.com		2024-04-29	1 of 4

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 045226 0011 Rev. 00

Reference: 713280314

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000018734

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 045226 0011 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-04-29

TÜV SÜD Product Service GmbH
Medical and Health Services

Angelika Harndt (29. April 2024 15:12 GMT+2)

Angelika Harndt
~~Conformity Assessment Responsible (CARE)~~
Regulatory Client Associate (RCA)

TÜV SÜD Product Service GmbH
Medical and Health Services

Christian Schroeder (30. April 2024 07:24 GMT+2)

Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 Basic UDI-DI: EWHITWGEL0028N (6712, 6622, 6662, 6702, 6812, 6832, 3102, 3103, 3104, 3106, 5711, 5621, 5661, 5701, 5721, 5511, 5811, 5821, 5831, 5921, 5941, 5715, 3501, [redacted], 5696)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2 045226 0007 Rev. 01; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 2 Basic UDI-DI: EWHITWGEL0018L (6612, 6602, 3100, 5611, 5691, 3500, [redacted]	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2 045226 0007 Rev. 01; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 Basic UDI-DI: EWHITWGP001U5 (5011, 5010, 3480, 3481)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☐ Certification as follows: or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-04-29	713280314	Initial issue