Manufacturer:

DENTSCARE LTDA

Av. Edgar Nelson Meister, 474 - Distrito Industrial - 89219-501 – Joinville – SC – Brazil

Technical Responsible: Friedrich Georg Mittelstädt

Contact details: ra@fgmdentalgroup.com

Single Registration Number: BR-MF-000004013

Trademark: FGM®

Authorized Representative:

Nuno Flores - Al. Bonifacio Lazaro Lozano, 3 – Piso 0 – C, 2780-125 Oeiras / Portugal

Contact details: Tel: (351) 21 4439292, ec.rep@fgm.ind.br

Single Registration Number: PT-AR-000003118

Notified Body:

BSI – Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

Notified Body number: 2797

Certificate number: MDR 759293 – Annex IX, Chapter I and III - Conformity assessment based on a quality management system and assessment of the technical documentation.

Product list:

PRODUCT NAME	INTENDED PURPOSE	BASIC UDI-DI
Ambar	A material primarily intended to be used as a bonding-promoting substance between tooth structure and restorative materials.	78996338ADS001VL
Ambar APS		78996338ADS002VN
Ambar Universal APS		78996338ADS003VQ
Ambar Universal APS Plus		78996338ADS007VY
Allcem	Adhesive cementation of indirect anterior and posterior restorations.	78996338CEM001VF
Allcem Core		78996338CEM002VH
Allcem Veneer APS	Adhesive cementation of indirect translucent veneers.	78996338CEM003VK
PrimmaArt	Fabrication of temporaries and long-term temporaries: crowns, bridges, inlays, onlays and veneers.	78996338RST007AC
Assist APS Modeling	Restorative material used for the purpose of treatment, attenuation or compensation of an injury or a deficiency, with the objective of efficiently restoring the form (anatomy), function and aesthetics of the parts of the compromised tooth structure.	78996338RST021A6
Assist APS Opaquer		78996338RST020A4
Brava		78996338RST0019Y
VoxelPrint Ceramic		78996338RST019AK
Elóra APS		78996338RST017AF
Llis		78996338RST002A2
Opallis		78996338RST003A4

Opus Bulk Fill APS		78996338RST005A8
Vittra APS		78996338RST008AE
Vittra APS Unique		78996338RST009AG
Vittra APS Flow		78996338RST018AH
Vittra APS Unique Flow		78996338RST016AD
Opallis Flow		78996338RST004A6
Opus Bulk Fill Flow APS		78996338RST006AA
Orthocem	Material used to bond metal, polycarbonate or ceramic brackets to the enamel surface of the tooth.	78996338CEM005VP
Ortho Bite	Material used for occlusal stop and band cementation.	78996338CEM006VR
White Post	To provide additional intraradicular retention for restoration of a tooth with insufficient residual structure, to efficiently restore the form (anatomy), *function and aesthetics of the* compromised tooth structure.	78996338FGP001XZ
Whitepost System		78996338FGP002Y3

(for a complete list, check annex I)

Risk Class: IIa

This EU Declaration of conformity is issued under the sole responsibility of manufacturer: Dentscare Ltda. The devices covered by the present EU Declaration are in conformity with the (EU) MDR 2017/745.

Bianca de Oliveira Mittelstädt
CEO

Tiago Ribeiro
Person Responsible for Regulatory Compliance

Place: Joinville, Brazil

Annex I

List of Product's Code

- **Ambar**

4000004238	AMBAR 2ML
4000019356	AMBAR 4ML CE
4000016278	AMBAR 6ML (RU)
4000019357	AMBAR 6ML CE

- **Ambar APS**

4000020028	AMBAR APS 6ML (NORD)
4000055799	AMBAR APS 6ML (RU)
4000019358	AMBAR APS 6ML CE

- **Ambar Universal APS**

4000020029	AMBAR UNIV APS 5ML (NORD)
4000055800	AMBAR UNIV APS 5ML (RU)
4000019361	AMBAR UNIV APS 5ML CE

- **Ambar Universal APS Plus**

4000055931	AMBAR UNIV APS PLUS 3ML

- **Allcem**

4000019276	ALLCEM A1 B/CAT 5G CE
4000002625	ALLCEM A1 BASE 2,5G CE
4000019277	ALLCEM A2 B/CAT 5G CE
4000002626	ALLCEM A2 BASE 2,5G CE
4000019278	ALLCEM A3 B/CAT 5G CE
4000002402	ALLCEM A3 BASE 2,5G CE
4000002403	ALLCEM CATALISADOR 2,5G
4000019279	ALLCEM TRANS B/CAT 5G CE
4000002730	KIT PONTS AUTOM ALLCEM 20UN

- **Allcem Core**

4000005700	ALLCEM CORE A1 6G
4000019280	ALLCEM CORE A1 6G CE
4000005701	ALLCEM CORE A2 6G
4000019281	ALLCEM CORE A2 6G CE
4000005702	ALLCEM CORE A3 6G
4000019282	ALLCEM CORE A3 6G CE
4000019283	ALLCEM CORE OPAQUE PEARL 6G CE
4000007094	KIT PONTS AUTOM CORE 10UN

- **Allcem Veneer APS**

4000019284	ALLCEM VENEER APS A1 2,5G CE
4000019285	ALLCEM VENEER APS A2 2,5G CE
4000019286	ALLCEM VENEER APS A3 2,5G CE
4000019287	ALLCEM VENEER APS E BLEACH M 2,5G CE
4000019288	ALLCEM VENEER APS OP WHITE 2,5G CE
4000019289	ALLCEM VENEER APS TRANS 2,5G CE
4000056583	ALLCEM VENEER APS XOW 2,5G

- **Assist APS Modeling**

4000055965	ASSIST APS MODELING 2G

- **Assist APS Opaquer**

4000055971	ASSIST APS OPAQUER PINK 2G
4000055972	ASSIST APS OPAQUER UNIVERSAL 2G
4000055973	ASSIST APS OPAQUER OW 2G

- **Brava**

4000013954	BRAVA BLOCK A1 HT 14L SIRONA
4000013847	BRAVA BLOCK A1 LT 14L SIRONA
4000013955	BRAVA BLOCK A2 HT 14L SIRONA
4000013948	BRAVA BLOCK A2 LT 14L SIRONA
4000013956	BRAVA BLOCK A3 HT 14L SIRONA
4000013949	BRAVA BLOCK A3 LT 14L SIRONA
4000013950	BRAVA BLOCK A3,5 LT 14L SIRONA
4000013957	BRAVA BLOCK B1 HT 14L SIRONA
4000013951	BRAVA BLOCK B1 LT 14L SIRONA
4000013952	BRAVA BLOCK BLEACH 14L SIRONA
4000013953	BRAVA BLOCK C2 LT 14L SIRONA

- **VoxelPrint Ceramic**

4000056595	VOXELPRINT CERAMIC A1 LT 150G
4000056051	VOXELPRINT CERAMIC A1-LT 250 G
4000056052	VOXELPRINT CERAMIC A2-LT 250 G
4000056573	VOXELPRINT CERAMIC A2-MT 250 G
4000056053	VOXELPRINT CERAMIC A3-LT 250 G
4000056597	VOXELPRINT CERAMIC B1 HT 150G
4000056596	VOXELPRINT CERAMIC B1 MT 150G
4000056056	VOXELPRINT CERAMIC B1-HT 250 G
4000056049	VOXELPRINT CERAMIC B1-LT 250 G
4000056575	VOXELPRINT CERAMIC B1-MT 250 G
4000056050	VOXELPRINT CERAMIC B2-LT 250 G
4000056598	VOXELPRINT CERAMIC BL HT 150G
4000056065	VOXELPRINT CERAMIC BL-HT 250 G
4000056048	VOXELPRINT CERAMIC BL-LT 250 G

4000056574	VOXELPRINT CERAMIC BL-MT 250 G
4000056930	VOXELPRINT CERAMIC A3-MT 250G
4000056976	VOXELPRINT CERAMIC CAPS A1-LT
4000056977	VOXELPRINT CERAMIC CAPS A2-LT
4000056978	VOXELPRINT CERAMIC CAPS A3-LT
4000056979	VOXELPRINT CERAMIC CAPS BL-LT
4000056980	VOXELPRINT CERAMIC CAPS B1-LT
4000056981	VOXELPRINT CERAMIC CAPS B2-LT
4000056982	VOXELPRINT CERAMIC CAPS BL-HT
4000056983	VOXELPRINT CERAMIC CAPS B1-HT
4000056984	VOXELPRINT CERAMIC CAPS A2-MT
4000056985	VOXELPRINT CERAMIC CAPS A3-MT
4000056986	VOXELPRINT CERAMIC CAPS BL-MT
4000056987	VOXELPRINT CERAMIC CAPS B1-MT

- **PrimmaArt**

4000055228	PRIMMA ART BLEACH 7G CE
4000055227	PRIMMA ART BLEACH 75G CE
4000055224	PRIMMA ART B1 7G CE
4000055223	PRIMMA ART B1 75G CE
4000055211	PRIMMA ART A3 7G CE
4000055218	PRIMMA ART A3 75G CE
4000055216	PRIMMA ART A2 7G CE
4000055219	PRIMMA ART A2 75G CE
4000055217	PRIMMA ART A1 7G CE
4000055213	PRIMMA ART A1 75G CE
4000023736	KIT PONT PRIMMA ART REFIL 7G 5UN
4000055257	KIT PONT PRIMMA ART REFIL 7G 20UN

- **Llis**

4000055464	LLIS CAPS DA1
4000055462	LLIS CAPS DA3,5
4000055454	LLIS CAPS DB2
4000055461	LLIS CAPS EA1
4000019407	LLIS DA1 4G CE FDA
4000019408	LLIS DA2 4G CE FDA
4000019409	LLIS DA3 4G CE FDA
4000019410	LLIS DA3,5 4G CE FDA
4000019411	LLIS DB2 4G CE FDA
4000019412	LLIS EA1 4G CE FDA
4000019413	LLIS EA2 4G CE FDA
4000019414	LLIS EA3 4G CE FDA
4000019415	LLIS EA3,5 4G CE FDA
4000019416	LLIS EA4 4G CE FDA
4000019417	LLIS EB1 4G CE FDA
4000019418	LLIS EB2 4G CE FDA
4000019419	LLIS EB3 4G CE FDA
4000019420	LLIS EC2 4G CE FDA
4000019421	LLIS EC3 4G CE FDA
4000019422	LLIS INCISAL 4G CE FDA
4000056010	LLIS BODY A1 4G
4000056011	LLIS BODY A2 4G
4000056012	LLIS BODY A3 4G

- **Opallis**

4000055431	OPALLIS BW WHITE 4G (IR)
4000016905	OPALLIS CAPS D BLEACH CE
4000020030	OPALLIS CAPS DA1 (NORD)
4000020031	OPALLIS CAPS DA2 (NORD)
4000016886	OPALLIS CAPS DA2 CE
4000020032	OPALLIS CAPS DA3 (NORD)
4000016887	OPALLIS CAPS DA3 CE
4000020033	OPALLIS CAPS DA3,5 (NORD)
4000016888	OPALLIS CAPS DA3,5 CE
4000020087	OPALLIS CAPS DA4 (NORD)
4000020034	OPALLIS CAPS DB1 (NORD)
4000016889	OPALLIS CAPS DB1 CE
4000020035	OPALLIS CAPS DB2 (NORD)
4000016890	OPALLIS CAPS DB2 CE
4000020036	OPALLIS CAPS DC2 (NORD)
4000016891	OPALLIS CAPS DC2 CE
4000016903	OPALLIS CAPS E BLEACH H CE
4000016904	OPALLIS CAPS E BLEACH M CE
4000020037	OPALLIS CAPS EA1 (NORD)
4000016892	OPALLIS CAPS EA1 CE
4000020038	OPALLIS CAPS EA2 (NORD)
4000016893	OPALLIS CAPS EA2 CE
4000020039	OPALLIS CAPS EA3 (NORD)
4000016894	OPALLIS CAPS EA3 CE
4000020040	OPALLIS CAPS EA3,5 (NORD)
4000016895	OPALLIS CAPS EA3,5 CE
4000020081	OPALLIS CAPS EA4 (NORD)
4000020041	OPALLIS CAPS EB1 (NORD)
4000016896	OPALLIS CAPS EB1 CE
4000020042	OPALLIS CAPS EB2 (NORD)
4000016897	OPALLIS CAPS EB2 CE
4000020083	OPALLIS CAPS EB3 (NORD)
4000020043	OPALLIS CAPS EC2 (NORD)
4000016898	OPALLIS CAPS EC2 CE
4000020085	OPALLIS CAPS EC3 (NORD)
4000016906	OPALLIS CAPS ODONTOP A0,5 CE
4000016907	OPALLIS CAPS ODONTOP B0,5 CE

4000020662	OPALLIS CAPS OPAQUE PEARL (NORD)
4000016902	OPALLIS CAPS OPAQUE PEARL CE
4000020660	OPALLIS CAPS OPAQUE WHITE (NORD)
4000016901	OPALLIS CAPS OPAQUE WHITE CE
4000020661	OPALLIS CAPS T BLUE (NORD)
4000016899	OPALLIS CAPS T BLUE CE
4000016900	OPALLIS CAPS T NEUTRAL CE
4000019438	OPALLIS D BLEACH 2G CE
4000019428	OPALLIS DA1 4G CE
4000019429	OPALLIS DA2 4G CE
4000019430	OPALLIS DA3 4G CE
4000019431	OPALLIS DA3,5 4G CE
4000019432	OPALLIS DA4 2G CE
4000019433	OPALLIS DB1 4G CE
4000019434	OPALLIS DB2 4G CE
4000019436	OPALLIS DC2 2G CE
4000019450	OPALLIS E BLEACH H 2G CE
4000019449	OPALLIS E BLEACH L 2G CE
4000019451	OPALLIS E BLEACH M 2G CE
4000019439	OPALLIS EA1 4G CE
4000019440	OPALLIS EA2 4G CE
4000019441	OPALLIS EA3 4G CE
4000019442	OPALLIS EA3,5 4G CE
4000019443	OPALLIS EA4 2G CE
4000019444	OPALLIS EB1 4G CE
4000019445	OPALLIS EB2 4G CE
4000019446	OPALLIS EB3 2G CE
4000019447	OPALLIS EC2 2G CE
4000019448	OPALLIS EC3 2G CE
4000055975	OPALLIS EBL1 2G
4000055977	OPALLIS EBL2 2G
4000055978	OPALLIS EBL3 2G
4000055979	OPALLIS DBL1 2G
4000055980	OPALLIS DBL2 2G
4000055981	OPALLIS DBL3 2G
4000055680	OPALLIS A1 BODY 4G CE FDA
4000055681	OPALLIS A2 BODY 4G CE FDA
4000055679	OPALLIS A3 BODY 4G CE FDA
4000019423	OPALLIS KIT BASICO CE
4000019613	OPALLIS ODONTOP A0,5 2G CE
4000019614	OPALLIS ODONTOP B0,5 2G CE
4000019456	OPALLIS OP PEARL 2G CE
4000019457	OPALLIS OP WHITE 2G CE
4000019452	OPALLIS T BLUE 2G CE
4000019455	OPALLIS T NEUTRAL 2G CE

4000055432	OPALLIS XBW WHITE 4G (IR)

- **Vittra APS**

4000021677	VITTRA APS CAPS DA0 CE
4000021678	VITTRA APS CAPS DA1 CE
4000021679	VITTRA APS CAPS DA2 CE
4000021383	VITTRA APS CAPS DA3 CE
4000021680	VITTRA APS CAPS DA3,5 CE
4000021687	VITTRA APS CAPS E BLEACH CE
4000021683	VITTRA APS CAPS EA1 CE
4000021684	VITTRA APS CAPS EA2 CE
4000021685	VITTRA APS CAPS EA3 CE
4000021686	VITTRA APS CAPS EB1 CE
4000021688	VITTRA APS CAPS TRANS N CE
4000021689	VITTRA APS CAPS TRANS OPL CE
4000055940	VITTRA APS CAPS DB1
4000055941	VITTRA APS CAPS DBL1
4000055942	VITTRA APS CAPS DBL2
4000055943	VITTRA APS CAPS DBL3
4000055944	VITTRA APS CAPS DBL4
4000055946	VITTRA APS CAPS EA3.5
4000055947	VITTRA APS CAPS EBL1
4000055948	VITTRA APS CAPS EBL2
4000055949	VITTRA APS CAPS EBL3
4000019384	VITTRA APS DA0 2G CE
4000055599	VITTRA APS EBL1 4G
4000055600	VITTRA APS EBL2 4G
4000055726	VITTRA APS EBL3 4G
4000055607	VITTRA APS EA3,5 4G
4000055609	VITTRA APS DBL1 4G
4000055610	VITTRA APS DBL2 4G
4000055727	VITTRA APS DBL3 4G
4000055611	VITTRA APS DB1 4G
4000055955	VITTRA APS DBL4 4G
4000055956	VITTRA APS EBL4 4G
4000019385	VITTRA APS DA1 4G CE
4000019386	VITTRA APS DA2 4G CE
4000019387	VITTRA APS DA3 4G CE
4000019388	VITTRA APS DA3,5 4G CE
4000019389	VITTRA APS DA4 2G CE
4000019390	VITTRA APS DA5 2G CE
4000019391	VITTRA APS E BLEACH 4G CE
4000019392	VITTRA APS EA1 4G CE
4000019393	VITTRA APS EA2 4G CE
4000019394	VITTRA APS EA3 4G CE
4000019395	VITTRA APS EB1 4G CE
4000019399	VITTRA APS TRANS N 2G CE

4000019398	VITTRA APS TRANS OPL 2G CE
4000019397	VITTRA APS VH 2G CE
4000019396	VITTRA APS VM 2G CE

- **Vittra APS Unique**

4000055452	VITTRA APS CAPS UNIQUE
4000055261	VITTRA APS UNIQUE 2G CE
4000055212	VITTRA APS UNIQUE 4G CE

- **Opus Bulk Fill APS**

4000019369	OPUS B FILL APS A2 4G CE
4000019370	OPUS B FILL APS A3 4G CE
4000019368	OPUS B FILL APS A1 4G CE
4000021694	OPUS B FILL APS CAPS A3 CE
4000021692	OPUS B FILL APS CAPS A1 CE
4000021382	OPUS B FILL APS CAPS A2 CE

- **Elóra APS**

4000056236	ELORA APS A1 4G
4000056237	ELORA APS A2 4G
4000056240	ELORA APS A3 4G
4000056241	ELORA APS A3.5 4G
4000056242	ELORA APS B1 4G
4000056243	ELORA APS BL 4G
4000056246	ELORA APS DA1 4G
4000056247	ELORA APS DA3 4G
4000056600	ELORA APS DB1 4G
4000056245	ELORA APS TRANS 2G
4000056601	ELORA APS WE 2G
4000056244	ELORA APS XBL 4G

- **Opallis Flow**

4000019380	OPALLIS FLOW A0,5 2G CE
4000020541	OPALLIS FLOW A1 2G (NORD)
4000020859	OPALLIS FLOW A1 2G (RU)
4000019374	OPALLIS FLOW A1 2G CE
4000020542	OPALLIS FLOW A2 2G (NORD)
4000020880	OPALLIS FLOW A2 2G (RU)
4000019375	OPALLIS FLOW A2 2G CE
4000020543	OPALLIS FLOW A3 2G (NORD)
4000020866	OPALLIS FLOW A3 2G (RU)
4000019376	OPALLIS FLOW A3 2G CE
4000020548	OPALLIS FLOW B0,5 2G (NORD)
4000019381	OPALLIS FLOW B0,5 2G CE
4000020544	OPALLIS FLOW OA3,5 2G (NORD)
4000020865	OPALLIS FLOW OA3,5 2G (RU)
4000019377	OPALLIS FLOW OA3,5 2G CE
4000020546	OPALLIS FLOW OP 2G (NORD)
4000055339	OPALLIS FLOW OP 2G (RU)
4000019483	OPALLIS FLOW OP 2G (UY)
4000019379	OPALLIS FLOW OP 2G CE
4000019378	OPALLIS FLOW T 2G CE

- **Opus Bulk Fill Flow APS**

4000055898	OPUS B FILL FLOW APS A1 2G (RU)
4000019371	OPUS B FILL FLOW APS A1 2G CE
4000055899	OPUS B FILL FLOW APS A2 2G (RU)
4000019372	OPUS B FILL FLOW APS A2 2G CE
4000055900	OPUS B FILL FLOW APS A3 2G (RU)
4000019373	OPUS B FILL FLOW APS A3 2G CE

- **Vittra APS Flow**

4000056567	VITTRA APS FLOW A1 2G
4000056566	VITTRA APS FLOW A2 2G
4000056565	VITTRA APS FLOW A3 2G
4000056564	VITTRA APS FLOW B1 2G
4000056563	VITTRA APS FLOW BL 2G
4000056561	VITTRA APS FLOW OA2 2G
4000056560	VITTRA APS FLOW TRANS 2G
4000056562	VITTRA APS FLOW XBL 2G

- **Vittra APS Unique Flow**

4000055624	VITTRA APS UNIQUE FLOW

- **Orthocem**

4000055253	ORTHOCEM RASTREADOR + CONDAC 37%
4000055254	ORTHOCEM RASTREADOR + CONDAC 37% (MX)
4000055255	ORTHOCEM RASTREADOR

- **Ortho Bite**

4000019365	ORTHO BITE BLUE CE FDA (U)

- **White Post**

4000019340	WHITE POST DC 0,5 INTRO CE
4000019342	WHITE POST DC 2 INTRO CE
4000019343	WHITE POST DC INTRO 3
4000019344	WHITE POST DC 0,5 CE
4000019345	WHITE POST DC 1 CE
4000019346	WHITE POST DC 2 CE
4000019347	WHITE POST DC 3 CE
4000019349	WHITE POST DC E KIT 25UN CE
4000019350	WHITE POST DC E 0,5 INTRO CE

4000019352	WHITE POST DCE INTRO 2 CE
4000019353	WHITE POST DC E 0,5 CE
4000019354	WHITE POST DC E 1 CE
4000019355	WHITE POST DC E 2 CE

- **Whitepost System**

4000055395	WHITEPOST SYSTEM DC E 0,5 INTRO
4000055340	WHITEPOST SYSTEM DC FIT 0,4 INTRO
4000055282	WHITEPOST SYSTEM DC 1 REFIL
4000055281	WHITEPOST SYSTEM DC 1 INTRO
4000055278	WHITEPOST SYSTEM DC 2 INTRO
4000055275	WHITEPOST SYSTEM DC E 2 INTRO
4000055273	WHITEPOST SYSTEM DC 3 INTRO
4000055272	WHITEPOST SYSTEM DC 2 REFIL
4000055270	WHITEPOST SYSTEM DC FIT 0,4 REFIL
4000055269	WHITEPOST SYSTEM DC E 0,5 REFIL
4000055268	WHITEPOST SYSTEM DC 0,5 REFIL
4000055276	WHITEPOST SYSTEM DC E 2 REFIL
4000055283	WHITEPOST SYSTEM DC 0,5 INTRO
4000055319	WHITEPOST SYSTEM DC E KIT 25UN
4000055317	WHITEPOST SYSTEM DC KIT 25UN
4000055280	WHITEPOST SYSTEM DC E 1 REFIL
4000055279	WHITEPOST SYSTEM DC E 1 INTRO
4000055271	WHITEPOST SYSTEM DC 3 REFIL
4000055929	WHITEPOST SYSTEM DC 0,5 / 1 REFIL MIX