Document Number	Rev	Document Title
DOC- 004	**0**	***MDD CE Declaration of Conformity for Elite***

Product Family Name:	Hydrafacial MD® Systems
Device Part Number:	Hydrafacial MD® Elite: 70290-03-01 NOTE: Devices suffixed with FRC or TUFRC are refurbished devices as per MDD Article 1 (f) and MDR Article 2 (31)
Basic UDI-DI (BUDI-DI) **UDI-DI**	BUDI-DI: Hydrafacial™ Elite Device Family: 081000753ELI7D UDI-DI: 70290-03-01: 00810007531311 – Elite Family 70290-03-01-FRC: 00810007534381 – Elite Family 70290-03-01-TUFRC: 00810007534497 – Elite Family
Intended Purpose:	The System is intended to exfoliate the upper layers of the skin. Indication: Mild to moderate acne, i.e. acne vulgaris, comedonal acne (blackheads and whiteheads), superficial acne scarring.
GMDN Code:	11177 Skin Abrasion Unit
UMDNS Code:	11177 Dermabrasion Unit
MDA Code:	0318 - Other active non-implantable devices
MDS Code:	1009 - Devices incorporating software / utilising software / controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices
MDT Code:	2001 - Devices manufactured using metal processing 2002 - Devices manufactured using plastic processing 2010 - Devices manufactured using electronic components includir communication devices 2011 - Devices which require packaging, including labelling
EMDN Code:	Z12040299 – General medicine therapeutic treatment instruments – -other

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Applicable Council Regulation:	Medical Device Directive 93/42/EEC amended by 2007/47/EC. Transitioning to EU Medical Device Regulation 2017/745, Article 120 (Regulation (EU) 2023/607)
Risk Classification:	Class IIa, Rule 11, MDD Annex IX. Class IIa (Rule 9, MDR, Annex VIII)

Harmonized Standards to which conformity is declared (select all that apply):

Safety:	IEC 60601-1:2005 + A1:2012 + A2:2020
	EN 60601-1:2006 + A1:2013 + A2:2021
EMC:	IEC 60601-1-2:2014 + A1:2020
	EN 60601-1-2:2015
Software:	EN 62304:2006 + A1:2015
	IEC 62304:2006
Medical Device QMS:	EN ISO 13485:2016
Biocompatibility:	EN ISO 10993
RoHS:	RoHS 3 (EU 2015/863): EN IEC 63000:2018

Manufacturer:	Hydrafacial LLC 3600 E Burnett Ave Long Beach, CA 90815, USA Toll Free: +1 800 603 4996 T: +1 562 597 0102
SRN	US-MF-000004431
Authorized Representative in EU:	EC Rep Ltd 5 Fitzwilliam Square East Dublin 2, D02 R744, Ireland Tel: +353 89 225 1951 Email: info@ecrep.ie **SRN**: IE-AR-000003995

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Responsible Person in the UK:	Responsible Person Ltd Summit House, 4-5 Mitchell Street Edinburgh, EH6 7BD, UK Tel: +44 7543 672 888 Email: info@responsible-person.co.uk
Authorized Representative in CH:	E C Rep GmbH Max-Högger-Strasse 6, 8048 Zürich. Tel: +41 44 585 32 00 Email: info@ch-rep.info **SRN**: CHRN-AR-20003319
EU Importer:	MedEnvoy Global B.V. Prinses Margrietplantsoen 33 - Suite 123 2595 AM The Hague The Netherlands Tel: +1 512-256-0570 Email: verification@medenvoyglobal.com **SRN**: NL-IM-000000248
Notified Body:	SGS Belgium NV SGS House – Noorderlaan 87 (RPR Antwerpen BTW BE 0404.882.750), Antwerp 2030, Belgium. Tel: +32 3 545 44 00

This product carries the CE Mark: CE 1639

SGS EC Certificate #: US 21/819944231

Date MDD CE Mark was first affixed: October 2007

This Device Family has been assessed with respect to the conformity assessment procedures described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC, as amended, and found to comply.

We declare, under our sole responsibility, that the above-mentioned products conform to the specified Directives and Standards and is eligible to carry the CE Mark. The Device History File is retained at the premises of the Manufacturer and its Authorized Representative.

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DOC- 004	**0**	***MDD CE Declaration of Conformity for Elite***

Signed for and on behalf of: HydraFacial, LLC
Place of Issue: Long Beach, California, United States of America

Signature of Authorized Person:

Date Signed: 29 November 2025
Name: Loraine Argyle
Title: Regulatory Affairs Manager
Hydrafacial LLC

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Addendum 1
Product Family Name:

Accessories are Class I, Rule 1 devices in accordance with MDD Annex IX and MDR Annex VIII .

Part Number	Product Name	Class	BUDI-DI	UDI-DI
74111	HydroPeel Tip, Large Clear	I	081000753TIP9V	00810007530901
74112	HydroPeel Tip, Large Blue	I	081000753TIP9V	00810007530918
74114	HydroPeel Tip, Small Teal	I	081000753TIP9V	00810007530925
74275	HydroPeel Tip, Orange Aggression	I	081000753TIP9V	00810007530932
70218	HydroPeel Tip, Body Blue	I	081000753TIP9V	00810007530895
74462	HydroPeel Tip, Purple Aggression	I	081000753TIP9V	00810007530949
7400000	Hydrafacial Keravive Tip	I	081000753TIP9V	00810007531045
7200114	Perk Rollerball Tip	I	081000753TIP9V	00810007532967
7200225	Hydrafacial Lip Tip	I	081000753TIP9V	00810007534756
7200226	Hydrascalp Nourish Tip	I	081000753TIP9V	00810007534770
7200227	Hydrascalp Purify Tip	I	081000753TIP9V	00810007534763
70301	Wet Diamond Kit	I	081000753TIP9V	00810007533797
70185	Hydrafacial Cleaning Caps	I	081000753CAP6G	00810007531328
7000131	Syndeo Hydrafacial Lymphatic Kit	I	081000753LYM9X	00810007532387
70144	Elite Hydrafacial Lymphatic Kit	I	081000753LYM9X	00810007532127

GMDN Code: 11177 Skin Abrasion Unit

UMDNS Code: 11177 Dermabrasion Unit

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MDN Code: 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices

EMDN Code: Z12040299 – General medicine therapeutic treatment instruments – other

Applicable Council Regulation: Medical Device Directive 93/42/EEC amended by 2007/47/EC and Medical Device Regulation 2017/745
Risk Classification: Class I, Rule 1, MDD 93/42/EEC. Class I, Rule I, MDR 2017/745

This product carries the CE Mark: CE

Date CE Mark was first affixed: May 2021

This Device Family has been assessed with respect to the conformity assessment procedures described in MDD 93/42/EEC, as amended by 2007/47/EC, and MDR 2017/745 and found to comply.

We declare, under our sole responsibility, that the above-mentioned products conform to the specified Directives and Standards and is eligible to carry the CE Mark. The Device History File is retained at the premises of the Manufacturer and its Authorized Representative.

Signed for and on behalf of: HydraFacial, LLC
Place of Issue: Long Beach, California, United States of America

Signature of Authorized Person:

Date Signed: 29 November 2025
Name: Loraine Argyle
Title: Regulatory Affairs Manager
Hydrafacial LLC