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FOR THE HEALTH AUTHORITIES OF VIETNAM

Certificate n° 00005325

Valid until 02.06.2023

The SWISS AGENCY FOR THERAPEUTIC PRODUCTS, SWISSMEDIC, authorizes and supervises therapeutic products (medicinal products and medical devices). In Switzerland medical devices are regulated under the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; SR 812.21) and the Medical Devices Ordinance (MedDO; SR 812.213) which incorporates the European legislation. On the basis of the documents submitted, Swissmedic certifies that the medical device(s) specified hereunder can be placed on the market in Switzerland and its treaty countries without restrictions.

- see attached list of 4 page(s)

Companies involved in the manufacturing or the supplying of these medical devices:

- **Ordering company:** **Zimmer GmbH**, 8 Sulzerallee, 8404 Winterthur, CH (Role: Legal manufacturer)

Bern, 02.06.2020

Swiss Agency for Therapeutic Products

Medical Devices Division

Gerda Baeriswyl




010619

No.
Seen for legalization of
the above signature

Berne, **15 JUN 2020**

SWISS FEDERAL CHANCELLERY


Gaëlle Cafaro-Vullierat





ĐẠI SỨ QUÁN VIỆT NAM TẠI THỤY SỸ
EMBASSY OF VIET NAM IN SWITZERLAND

CHỨNG NHẬN / HỢP PHÁP HOÁ LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia: Việt Nam
Country
- Giấy tờ, tài liệu này
This public document
2. do Ông (Bà): Gaelle Cafaro-Vullierat ký
has been signed by
3. với chức danh:
acting in the capacity of
4. và con dấu của: Văn phòng Liên bang
bears the seal/stamp of
được chứng nhận / hợp pháp hoá lãnh sự
Certified
5. tại: BERN
at
6. ngày 19 / 06 / 2020
the
7. Cơ quan cấp: Embassy of Viet Nam in Switzerland
by
8. Số: 655 /CNLS/HPHLS
N^o

Ký tên và đóng dấu
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TL. ĐẠI SỨ
THAM TÁN



Nguyễn Thành Huy



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Hip implants

Avenir Hip System				
Item No.	Description	Class	Sterile	GMDN Code
01.06010.201	Avenir®, stem, standard, cemented, 1, taper 12/14	III	Yes	34190
01.06010.202	Avenir®, stem, standard, cemented, 2, taper 12/14	III	Yes	34190
01.06010.203	Avenir®, stem, standard, cemented, 3, taper 12/14	III	Yes	34190
01.06010.204	Avenir®, stem, standard, cemented, 4, taper 12/14	III	Yes	34190
01.06010.205	Avenir®, stem, standard, cemented, 5, taper 12/14	III	Yes	34190
01.06010.206	Avenir®, stem, standard, cemented, 6, taper 12/14	III	Yes	34190
01.06010.207	Avenir®, stem, standard, cemented, 7, taper 12/14	III	Yes	34190
01.06010.208	Avenir®, stem, standard, cemented, 8, taper 12/14	III	Yes	34190
01.06010.209	Avenir®, stem, standard, cemented, 9, taper 12/14	III	Yes	34190
01.06010.301	Avenir®, stem, lateral, cemented, 1, taper 12/14	III	Yes	34190
01.06010.302	Avenir®, stem, lateral, cemented, 2, taper 12/14	III	Yes	34190
01.06010.303	Avenir®, stem, lateral, cemented, 3, taper 12/14	III	Yes	34190
01.06010.304	Avenir®, stem, lateral, cemented, 4, taper 12/14	III	Yes	34190
01.06010.305	Avenir®, stem, lateral, cemented, 5, taper 12/14	III	Yes	34190
01.06010.306	Avenir®, stem, lateral, cemented, 6, taper 12/14	III	Yes	34190
01.06010.307	Avenir®, stem, lateral, cemented, 7, taper 12/14	III	Yes	34190
01.06010.308	Avenir®, stem, lateral, cemented, 8, taper 12/14	III	Yes	34190
01.06010.309	Avenir®, stem, lateral, cemented, 9, taper 12/14	III	Yes	34190
01.06010.001	Avenir® Müller stem, standard, uncemented, HA, 1, taper 12/14	III	Yes	33581
01.06010.002	Avenir® Müller stem, standard, uncemented, HA, 2, taper 12/14	III	Yes	33581
01.06010.003	Avenir® Müller stem, standard, uncemented, HA, 3, taper 12/14	III	Yes	33581
01.06010.004	Avenir® Müller stem, standard, uncemented, HA, 4, taper 12/14	III	Yes	33581
01.06010.005	Avenir® Müller stem, standard, uncemented, HA, 5, taper 12/14	III	Yes	33581
01.06010.006	Avenir® Müller stem, standard, uncemented, HA, 6, taper 12/14	III	Yes	33581
01.06010.007	Avenir® Müller stem, standard, uncemented, HA, 7, taper 12/14	III	Yes	33581
01.06010.008	Avenir® Müller stem, standard, uncemented, HA, 8, taper 12/14	III	Yes	33581
01.06010.009	Avenir® Müller stem, standard, uncemented, HA, 9, taper 12/14	III	Yes	33581



Print No. - 200.214032 - Page 2/5





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Avenir Hip System				
Item No.	Description	Class	Sterile	GMDN Code
01.06010.101	Avenir® Müller stem, lateral, uncemented, HA, 1, taper 12/14	III	Yes	33581
01.06010.102	Avenir® Müller stem, lateral, uncemented, HA, 2, taper 12/14	III	Yes	33581
01.06010.103	Avenir® Müller stem, lateral, uncemented, HA, 3, taper 12/14	III	Yes	33581
01.06010.104	Avenir® Müller stem, lateral, uncemented, HA, 4, taper 12/14	III	Yes	33581
01.06010.105	Avenir® Müller stem, lateral, uncemented, HA, 5, taper 12/14	III	Yes	33581
01.06010.106	Avenir® Müller stem, lateral, uncemented, HA, 6, taper 12/14	III	Yes	33581
01.06010.107	Avenir® Müller stem, lateral, uncemented, HA, 7, taper 12/14	III	Yes	33581
01.06010.108	Avenir® Müller stem, lateral, uncemented, HA, 8, taper 12/14	III	Yes	33581
01.06010.109	Avenir® Müller stem, lateral, uncemented, HA, 9, taper 12/14	III	Yes	33581

-End list-

Hip instruments

Avenir Hip Stem Instruments				
Item No.	Description	Class	Sterile	GMDN Code
01.01559.128	trial head, S, ø 28, taper 12/14	Ila	No	58479
01.01559.132	trial head, S, ø 32, taper 12/14	Ila	No	58479
01.01559.136	trial head, S, ø 36, taper 12/14	Ila	No	58479
01.01559.228	trial head, M, ø 28, taper 12/14	Ila	No	58479
01.01559.232	trial head, M, ø 32, taper 12/14	Ila	No	58479
01.01559.236	trial head, M, ø 36, taper 12/14	Ila	No	58479
01.01559.328	trial head, L, ø 28, taper 12/14	Ila	No	58479
01.01559.332	trial head, L, ø 32, taper 12/14	Ila	No	58479
01.01559.336	trial head, L, ø 36, taper 12/14	Ila	No	58479
01.01559.428	trial head, XL, ø 28, taper 12/14	Ila	No	58479
01.01559.432	trial head, XL, ø 32, taper 12/14	Ila	No	58479
01.01559.436	trial head, XL, ø 36, taper 12/14	Ila	No	58479
01.06520.000	Avenir®, trial neck for Trunnionconnection, standard	Ila	No	58481
01.06520.100	Avenir®, trial neck for Trunnionconnection, lateral	Ila	No	58481

Print No. - 200.214032 - Page 3/5





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Avenir Hip Stem Instruments				
Item No.	Description	Class	Sterile	GMDN Code
01.06620.001	Avenir®, rasp with Trunnion connection,1	Ila	No	58481
01.06620.002	Avenir®, rasp with Trunnion connection,2	Ila	No	58481
01.06620.003	Avenir®, rasp with Trunnion connection,3	Ila	No	58481
01.06620.004	Avenir®, rasp with Trunnion connection,4	Ila	No	58481
01.06620.005	Avenir®, rasp with Trunnion connection,5	Ila	No	58481
01.06620.006	Avenir®, rasp with Trunnion connection,6	Ila	No	58481
01.06620.007	Avenir®, rasp with Trunnion connection,7	Ila	No	58481
01.06620.008	Avenir®, rasp with Trunnion connection,8	Ila	No	58481
01.06620.009	Avenir®, rasp with Trunnion connection,9	Ila	No	58481
01.06510.000	Avenir®, trial neck for rasp (MIS),standard	Ila	No	58481
01.06510.100	Avenir®, trial neck for rasp (MIS),lateral	Ila	No	58481
01.06610.001	Avenir®, MIS, modular rasp, 1	Ila	No	58481
01.06610.002	Avenir®, MIS, modular rasp, 2	Ila	No	58481
01.06610.003	Avenir®, MIS, modular rasp, 3	Ila	No	58481
01.06610.004	Avenir®, MIS, modular rasp, 4	Ila	No	58481
01.06610.005	Avenir®, MIS, modular rasp, 5	Ila	No	58481
01.06610.006	Avenir®, MIS, modular rasp, 6	Ila	No	58481
01.06610.007	Avenir®, MIS, modular rasp, 7	Ila	No	58481
01.06610.008	Avenir®, MIS, modular rasp, 8	Ila	No	58481
01.06610.009	Avenir®, MIS, modular rasp, 9	Ila	No	58481
6896	trial head, ø 28, S, taper 12/14	Ila	No	58479
6897	trial head, ø 28, M, taper 12/14	Ila	No	58479
6898	trial head, ø 28, L, taper 12/14	Ila	No	58479
01.01519.808	trial head, XL, ø 28, taper 12/14	Ila	No	58479
6836	trial head, S, ø 32, taper 12/14	Ila	No	58479
6837	trial head, M, ø 32, taper 12/14	Ila	No	58479
6838	trial head, L, ø 32, taper 12/14	Ila	No	58479
01.01519.208	trial head, XL, ø 32, taper 12/14	Ila	No	58479
01.01519.635	trial head, S, ø 36/-4, taper 12/14	Ila	No	58479
01.01519.636	trial head, M, ø 36/0, taper 12/14	Ila	No	58479
01.01519.637	trial head, L, ø 36/+4, taper 12/14	Ila	No	58479
01.01519.638	trial head, XL, ø 36/+8, taper 12/14	Ila	No	58479
5951	measuring cone, 1	Ila	No	44742
5952	measuring cone, 2	Ila	No	44742
5953	measuring cone, 3	Ila	No	44742
5954	measuring cone, 4	Ila	No	44742
5955	measuring cone, 5	Ila	No	44742



Print No. - 200.214032 - Page 4/5



Avenir Hip Stem Instruments				
Item No.	Description	Class	Sterile	GMDN Code
5958	measuring cone, 2.5	Ila	No	44742
5959	measuring cone, 3.5	Ila	No	44742
5961	measuring cone, 6 W	Ila	No	44742
5962	measuring cone, 7 W	Ila	No	44742
01.00001.001	handle for modular rasps, straight	I	No	44742
01.06010.910	Avenir®, base tray, plastic, empty	I	No	44742
01.06010.911	Avenir®, insert for plastic base tray(empty)	I	No	44742
70.00.01	bar, long	I	No	44742
70.08.89	awl	I	No	44742
72.13.02-10	box chisel	I	No	44742
75.11.00-02	handle for top	I	No	44742
78.00.38-28	repositioning top, ø 28	I	No	44742
78.00.38-32	repositioning top, ø 32	I	No	44742
78.00.38-36	repositioning top, ø 36	I	No	44742
01.06510.001	trial neck holder	I	No	44742
01.06010.900	Avenir®, tray for instruments, metal, empty	I	No	44742
01.06010.901	MIS, tray for handles, empty	I	No	44742
01.00029.031	tray cover (standard), grey	I	No	44742
00-7806-045-00	rasp handle for anterior approach	I	No	44742
01.00001.002	MIS, rasp handle, double offset, right	I	No	44742
01.00001.003	MIS, rasp handle, double offset, left	I	No	44742
01.06310.004	stem impactor	I	No	44742
78.00.38	synthetic top	I	No	44742
01.06808.300	extractor with sliding hammer	I	No	44742
5950	setting instrument with scale	I	No	44742

-End list-

GMDN code description

GMDN Code	GMDN Term Name
34190	Uncoated hip femur prosthesis, modular
33581	Coated hip femur prosthesis, modular
44742	Description: Joint prosthesis implantation kit, reusable
58479	Description: Femoral head trial prosthesis
58481	Description: Femoral stem trial prosthesis

-End list-

