

Simply the best fixation.



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DECLARATION OF CONFORMITY

We as manufacturer according the Medical Devices regulations 2002 and the Medical Devices (Amendment; EU Exit) Regulations 2020

Baitella AG, Thurgauerstrasse 70, CH-8050 Zürich
SRN: CH-MF-000017307

with Authorised UK Representative,

confinis (UK) RP Ltd
St John's Innovation Centre
Coweley Road, Cambridge
CB4 0WS
England, United Kingdom

Application reference: 2023020201294026

We declare under our sole responsibility that

FISSO medical articulated arms with quick central fixation and components

GMDN Code	Term	Basic UDI	Reference Number
37047	arm procedure positioner, reusable	76401525756PS200847	4646.x, 4670.x 6646.x, 6656.x
65180	operating table patient positioning set, reusable	76401525756PS200847	6740.x
41893	medical device service rail clamp	76401525727IPSa65767V 76401525706OPS7879JG	5.255-VE 5.780-VE, 5.752-VE, 5.750-VE, 5.280-VE, 5.750-x 5.252-VE, 5.251-VE, 5.240-VE
62379	surgical instrument assist arm system, manually-adjusted	76401525706OPS7879JG	3840.x, 3855.x
37041	breathing circuit tube holder	76401525727IPSa65767V	5.731, 5.721 3690.x, 3670.x, 3640.x, 3628.x 3590.x 2628.x
64146	surgical instrument assist arm structural component	76401525706OPS7879JG	3840.x, 3855.x 5.716, 5.731, 5.721
35504	blood pressure transducer holder	76401525727IPSa65767V	3640.x

of class I meets all applicable provisions.

Validity of this Declaration of Conformity until 09.10.2028

Baitella AG
Zurich, 09.10.2025



Edgar Schönbächler
CEO



Juan Rubiano
QM/RA Manager & PRRC