

Simply the best fixation.



Baitella AG
Thurgauerstrasse 70, CH-8050 Zurich, Switzerland
Phone +41 (0)44 305 80 00, Fax: +41 (0)44 305 80 05
info@baitella.com, www.fisso.com

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 ; Coweley Road; Cambridge; CB4 0 WS; 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
41893	medical device service rail clamp	76401525727IPSa65767V 76401525706OPS7879JG	5.255-VE 5.780-VE, 5.752-VE, 5.750-VE, 5.280-VE, 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	5.716, 5.731, 5.721
64146	surgical instrument assist arm structural component	76401525706OPS7879JG	3840.x, 3855.x
35504	blood pressure transducer holder	76401525727IPSa65767V	3640.x

of class I meets all applicable provisions.

Validity of this Declaration of Conformity until 30.06.2025

Baitella AG
Zürich, 21.04.2022

Pascal Weber
CEO

Dr. Thomas Bühler
Responsible Person for
Regulatory Compliance