

**Intersurgical S.p.A.**

Via T. Morandi, 12 - 41037 Mirandola (MO) Italy

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info@intersurgical.it www.intersurgical.it

Management  
System  
ISO 9001:2015  
EN ISO 13485:2016www.tuv.com  
ID 8000006840

## EU Declaration of Conformity

The undersigned **Intersurgical S.p.A. (SRN IT-MF-000010729)** having its legal office in Via T. Morandi n. 12, 41037 Mirandola (MO), - Italy, Fully Paid Stock Capital: € 760.865, registered at the Enterprises Register of Modena – Fiscal Code and VAT nbr. 02092530365, registered at the REA Office of Modena with nr. 264759, under the sole responsibility, as manufacturer of the following devices:

**N.I.V. MEDICAL DEVICES, CPAP AND ACCESSORIES****N.I.V. helmets –N.I.V. (CPAP) helmets****Model Castar (x):**

**CASTAR, CASTAR R, CASTAR ZIP, CASTAR LIGHT, CASTAR R LIGHT, CASTAR LIGHT ZIP, CASTAR R LIGHT ZIP, CASTAR NEXT, CASTAR R NEXT, CASTAR NEXT ZIP, CASTAR R NEXT ZIP, CASTAR UP, CASTAR R UP, CASTAR BASIC, CASTAR R BASIC, CASTAR AC, CASTAR INFANT, CASTAR INFANT BASIC, CASTAR INFANT LIGHT ZIP, CASTAR INFANT ZIP, CASTAR LIGHT INFANT, CASTAR LIGHT PED, CASTAR PED, CASTAR PED BASIC, CASTAR PED LIGHT ZIP, CASTAR PED ZIP, CASTAR R INFANT, CASTAR R INFANT LIGHT ZIP, CASTAR R INFANT ZIP, CASTAR R PED, CASTAR R PED BASIC, CASTAR R PED LIGHT ZIP, CASTAR R PED ZIP**

**BASIC UDI-DI: 80583230DCCASCHIKD**

Product codes are listed in the attachment

**DECLARES HEREBY THAT:**

- the above mentioned medical devices are in compliance with essential requirements of Medical Device Regulation (EU) 2017/745 (MDR);
- the above mentioned medical devices are classified as Medical Device in Class IIa in conformity with Attachment VIII of said Regulation in according to the classification rule 2;
- the medical devices described above are certified in conformity with **Attachment IX of Medical Device Regulation (EU) 2017/745 (MDR)**, under the supervision of the Notified Body N° 1936, TUV Rheinland Italia Srl, Via Mattel, 3, 20010 Pogliano Milanese (MI) with the release of the certificate (ITH 1344699 1);
- the applicable standards are mentioned in the Technical File stored in Intersurgical and it is available for the Competent Authorities;
- the above mentioned medical devices are manufactured and controlled according to internal procedures regulating the manufacturing process;
- the traceability of the above mentioned devices is assured according to the law;
- The Intersurgical Quality System is certified by the Notified Body TUV Rheinland Italia Srl, Via Mattel, 3, 20010 Pogliano Milanese (MI), according to the standards UNI EN ISO 9001 and UNI CEI EN ISO 13485.

Yours Faithfully,

**Place and date**Mirandola, 24/02/2023**Approved by Legal Representative  
And Managing Director**Stefano Bellarmi

Issue date: 24/02/2023

Valid until: 24/01/2028

**DCHELMETS/10**UK • Ireland • France • Germany • Spain • Portugal • Italy • Benelux • Sweden • Denmark • Lithuania • Russia • Czech Republic  
Turkey • South Africa • China • Japan • Taiwan • Philippines • USA • Canada • Colombia • Australia

Intersurgical S.p.A.

Cap. Soc. € 760.865,00 i.n. Iscriz. Registro Imprese di Modena, C.F. e P.IVA Nr. 02092530365 - Iscritta REA di Modena Nr. 264759 - PEC: intersurgical@legalmail.it

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**Product codes DCHELMETS/10**

CA0123XL/2	Hood for non invasive ventilation – CASTAR UP
CA012XXL/2	Hood for non invasive ventilation – CASTAR UP
CA012XL/2	Hood for non invasive ventilation – CASTAR UP
CA012L/2	Hood for non invasive ventilation – CASTAR UP
CA012M/2	Hood for non invasive ventilation – CASTAR UP
CA012S/2	Hood for non invasive ventilation – CASTAR UP
CA012XS/2	Hood for non invasive ventilation – CASTAR UP
CP2113XL/2R	Hood for non invasive ventilation – CASTAR R
CP211XXL/2R	Hood for non invasive ventilation – CASTAR R
CP211XL/2R	Hood for non invasive ventilation – CASTAR R
CP211L/2R	Hood for non invasive ventilation – CASTAR R
CP211M/2R	Hood for non invasive ventilation – CASTAR R
CP211S/2R	Hood for non invasive ventilation – CASTAR R
CP211XS/2R	Hood for non invasive ventilation – CASTAR R
CA0223XL/2R	Hood for non invasive ventilation – CASTAR R UP
CA022XXL/2R	Hood for non invasive ventilation – CASTAR R UP
CA022XL/2R	Hood for non invasive ventilation – CASTAR R UP
CA022L/2R	Hood for non invasive ventilation – CASTAR R UP
CA022M/2R	Hood for non invasive ventilation – CASTAR R UP
CA022S/2R	Hood for non invasive ventilation – CASTAR R UP
CA022XS/2R	Hood for non invasive ventilation – CASTAR R UP