



EC DECLARATION

OF CONFORMITY NO. CE 745-UK-2026136

QMS has examined the product and the related technical file as per Annex II and III of the products) and has been assessed according to the Declaration of Conformity as per Annex VI as presented and certifies that the below mentioned product complies with the applicable requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices ("MDR") for Class I Medical Devices and meet the transposition into national and international laws. All supporting documentations are retained under the premises of the manufacturer. QMS is exclusively responsible for the declaration of conformity. The Directive(s) and Standard or Specification as below.

Certificate Holder	M/S BACKHAUS INTERNATIONAL
Company Address	SMALL INDUSTRIAL ESTATE(S.I.E), 51310, SIALKOT, PAKISTAN.
Product Name	See Annex I
Classification	Product Categories (Medical Devices Class I) Please See Annexure-I List of Devices
Assessment Route	EC Declaration of Conformity (Annex IV of Regulation (EU) 2017 / 7 45)



Examined for Compliance with: Regulation (EU) 2017 /745

Reference: The classification rules in Annex VIII and Article 51 of the MDR

Relevant Standard(s)/Technical Specification: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices

Harmonized & Applicable Standards References: BS EN 1041:2008+A1:2013, EN ISO 13485:2016, EN ISO 10993-1:2018 This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration

Limitations: QMS has liabilities limited to the audit for certification of the products and in case of alteration of the products, not agreed upon by us, this declaration will lose its validity automatically.



Technical File Reference No.	CE-UK-2026-BI-24
Verification Report No.	CE2025.G.UK.06
Original Registration Date	November 06, 2024
Place, Date of Issue	Rome, November 06, 2024
Expiry Date of the Certificate	November 05, 2026



Blockchain ID

Authorised Signatory

Authorised Signatory

General Conditions for Certification Services: This registration was subject to the QMS terms and conditions, auditing and certification procedures. The certificate is subject to regular surveillance audits. To take care or the effectivity of certificate organization should have to successfully pass the audit. While all due care and competence was practiced in carrying out the assessment, QMS accepts only responsibility of the proven gross negligence. This certificate remains the property of QMS. The first certificate and every one copies shall be came or destroyed upon the request by QMS. This document is copy right protected. Content could not be duplicated without the prior written permission of QMS. Any misapplication, modification, deceit and fabrication is unlawful.

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OF CONFORMITY NO. CE 745-UK-2026136

List of product(s) attachment to the declaration of conformity

Manufacturer: M/S BACKHAUS INTERNATIONAL

Sr. No.	Product(s)	Article Number
Dental Instruments		
1.	Tooth Extracting Forceps	EU-MF-01
2.	Root Elevator	EU-MF-02
3.	Bone Rongeurs	EU-MF-03
4.	Bone Chisel	EU-MF-04
5.	Bone Curette	EU-MF-05
6.	Needle Holder	EU-MF-06
7.	Mouth Gag	EU-MF-07
8.	Dental Scaler	EU-MF-08
9.	Wax Knife	EU-MF-09
10.	Dental Dressing Forceps	EU-MF-10
11.	Rubber Dam Clamps Forceps	EU-MF-11
12.	Rubber Dam Punch Forceps	EU-MF-12
13.	Rubber Dam Clamp	EU-MF-13
14.	Orthodontic Plier	EU-MF-14
15.	Amalgam Instrument	EU-MF-15
16.	Caliper	EU-MF-16
17.	Rubber Dam Frame	EU-MF-17
18.	Dental Cheek Retractor	EU-MF-18
19.	Dental Surgical Scissor	EU-MF-19
20.	Crown Scissor	EU-MF-20
21.	Dental Syringe	EU-MF-21
22.	Dental Spatula	EU-MF-22
23.	Dental Mirror	EU-MF-23
24.	Bone File/Rasp	EU-MF-24
25.	Impression Tray	EU-MF-25
26.	Dental Articulator	EU-MF-26



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Manufacturer: M/S BACKHAUS INTERNATIONAL

Sr. No.	Product(s)	Article Number
Surgical Instruments		
27.	Scissor	EU-MF-27
28.	Dressing Forceps	EU-MF-28
29.	Mosquito Forceps	EU-MF-29
30.	Pean Forceps	EU-MF-30
31.	Kelly Forceps	EU-MF-31
32.	Crile Forceps	EU-MF-32
33.	Needle Holder	EU-MF-33
34.	Splinter Forceps	EU-MF-34
35.	Towel Clamp	EU-MF-35
36.	Sponge Forceps	EU-MF-36
37.	Thumb Forceps	EU-MF-37
38.	Tissue Forceps	EU-MF-38
39.	Retractor	EU-MF-39
40.	Hook	EU-MF-40
41.	Probe	EU-MF-41
42.	Vaginal Speculum	EU-MF-42
43.	Vaginal Dilator	EU-MF-43
44.	Biopsy Forceps	EU-MF-44
45.	Towel Forceps	EU-MF-45
46.	Otoscope Set	EU-MF-46
47.	Liposuction Cannula	EU-MF-47
48.	Laryngoscope Blade	EU-MF-48
49.	Laparoscopic instruments	EU-MF-49
50.	Ophthalmoscope	EU-MF-50
51.	Percussion Hammer	EU-MF-51
52.	Suction Cannula	EU-MF-52
53.	Scalpel Handle	EU-MF-53
54.	Scalpel	EU-MF-54
55.	Surgical Set	EU-MF-55
56.	Dissecting Kit	EU-MF-56



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證明書
الشهادات
Sertifikat
Zertifikat
Сертификат
Довідка
Certificado
Certificate



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Manufacturer: M/S BACKHAUS INTERNATIONAL

Sr. No.	Product(s)	Article Number
57.	Instrument Tray	EU-MF-57
58.	Sterilization/Disinfection Container	EU-MF-58
59.	Forceps Jar	EU-MF-59
60.	Emesis Bowl	EU-MF-60
61.	General Purpose Bowl	EU-MF-61
62.	Bedpan	EU-MF-62
63.	Bone Cutter	EU-MF-63
64.	Mallet	EU-MF-64
65.	Disposable Rasp	EU-MF-65
66.	Curette	EU-MF-66
67.	Bone Cutting Forceps	EU-MF-67
68.	Bone Holding Forceps	EU-MF-68
69.	Uterine Sound	EU-MF-69
70.	Surgical Spatula	EU-MF-70
71.	Disposable Scissor	EU-MF-71
72.	Disposable Forceps	EU-MF-72
73.	Disposable Handle	EU-MF-73



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