

Inspired by Science

Product overview

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serion\immunologics

Your Partner in Raw Material Sourcing



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Your Partner in Raw Material Sourcing

Based on more than 45 years of experience and success in infectious disease diagnostics, the division **SERION Immunologics** was created in 2013 to focus on the raw material business of Virion\Serion GmbH.

Founded in Germany in 1978, Virion\Serion is an expert in the manufacture and worldwide distribution of *in-vitro* diagnostics (IVD) for infectious diseases. Especially in the field of ELISA systems, Virion\Serion enjoys a particularly high reputation. With a subsidiary in China as well as a global network of distributors, Virion\Serion's diagnostic products are sold in over 100 countries worldwide. All IVD products are represented by the division SERION Diagnostics.

The core of the SERION Immunologics business is its product line SERION Antigens, representing the in-house antigen production of Virion\Serion and including native as well as recombinant antigens. Current antigen production processes cover everything from conventional cell culture for virus propagation and cultivation of bacterial pathogens, such as *B. pertussis* as native antigens, to advanced recombinant antigen production in *E. coli*, yeast and insect cells expression systems (Baculovirus and S2 insect cells).

In order to address the needs of IVD manufacturers, SERION plasma and SERION antibodies are important additions to the product portfolio of SERION Immunologics. These two product groups allow a quick and customer-specific choice of controls, calibrators and standards. Additionally, SERION customized also offers the possibility of special services such as ELISA plate coating and customized antigen or antibody development. Bovine serum albumin (BSA) was the first constituent of the product line SERION reagents. We ensure to continuosly expand our product portfolio of reagents, which includes e. g. new antigens, Rheumatoid Factor and customized requirements on request.

Products

SERION Immunologics manufactures and provides a wide range of diagnostic raw materials and services, which are categorized in the following product groups:

Raw Materials

- SERION antigens
- SERION plasma
- SERION antibodies
- SERION reagents

SRION customized

- Antigen and antibody development
- ELISA plate coating
- Buffer production
- Lyophilization

High flexibility, experienced employees and a competent customer support makes SERION Immunologics a strong and respected partner in the field of IVD related raw materials and components.

Samples available (Antigens, Plasma, Antibodies, RF, BSA).



Quality is our standard

Based on more than **45 years of experience and success** in infectious disease diagnostics, the division SERION Immunologics was created in 2013 to focus on the raw material business of Virion\Serion GmbH. The infectious disease diagnostic products in risk classes B and C have already been certified in accordance with **REGULATION (EU) 2017/746 (IVDR)**. All diagnostic medical devices are **CE marked**. In addition, the quality management system is certified according to **EN ISO 13485**.

Our company history

Founded in 1978, Virion\Serion GmbH has now, after **more than 45 years**, evolved from a distribution company for complement fixation test (CFT) reagents to a well-known and respected IVD manufacturer with one of the largest infectious disease portfolios for diagnosis of viral, bacterial, fungal and parasitic diseases worldwide.



1978

Foundation in Wuerzburg
Foundation of the Virion\Serion GmbH with the product line SERION CFT in Wuerzburg (Germany).

1981

Extension of the product portfolio
Introduction of a second product line SERION ELISA *classic* for the detection of antibodies against various pathogens.

1986

Founding of SERION Immundiagnostika GmbH
Founding of SERION Immundiagnostika GmbH for the worldwide export of our *in-vitro* diagnostics.

2000

CE certification
CE certification for the development, production and sale of our *in-vitro* diagnostics to ensure our consistently high quality standards.

2003

Location China
Founding of a representative office in Beijing and simultaneous registration of the entire ToRCH panel of the SERION ELISA *classic* product line in China.

2007

SERION Immunomat
Introduction of the laboratory device SERION Immunomat for highly effective automated processing and evaluation of SERION ELISA immunoassays.

2013

Introducing SERION Immunologics
Introduction of the SERION Immunologics division for the sale of high-quality raw materials, e.g. bulk antigens, disease state sera and monoclonal antibodies, as well as the offer of various services.

2015

Foundation of Virion\Serion Biotechnology (Shenzhen) Co.Ltd.
Foundation of Virion\Serion Biotechnology (Shenzhen) Co., Ltd. to further intensify activities on the Chinese market.

2018

Introduction of SERION Diagnostics
Introduction of the SERION Diagnostics division to further focus the activities of Virion\Serion GmbH in the field of *in-vitro* diagnostics.

2023

45 years of Virion\Serion
For 45 years, Virion\Serion has proven to be a reliable, competent and trustworthy partner for our customers worldwide.

Inspired by Dedication – this has always been the credo of Virion\Serion and its employees, right from the very beginning, and we want to live this claim in the future as well. For more than four decades now, Virion\Serion has proven to be a reliable, competent and trusted partner for our customers worldwide. All processes, services and products are managed in accordance with the EU directive 98/79/EC and IVD regulation (IVDR) 2017/746, under a certified quality management system according to EN ISO 13485, to ensure and maintain the highest quality of our products and services. All products are manufactured in Germany (Wuerzburg) and are distributed by our own field sales force in Germany and a network of distributors and partners worldwide.

Our aim is to bring value to our customers – with every product and service!

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SERION antigens

Critical raw materials, such as antigens, are key factors for establishing reproducible and robust immunodiagnostic test systems. SERION Immunologics produces a variety of high-class infectious disease antigens for ELISA, lateral flow diagnostics (LFD), bead based assays (e.g. CLIA), as well as non-IVD applications.

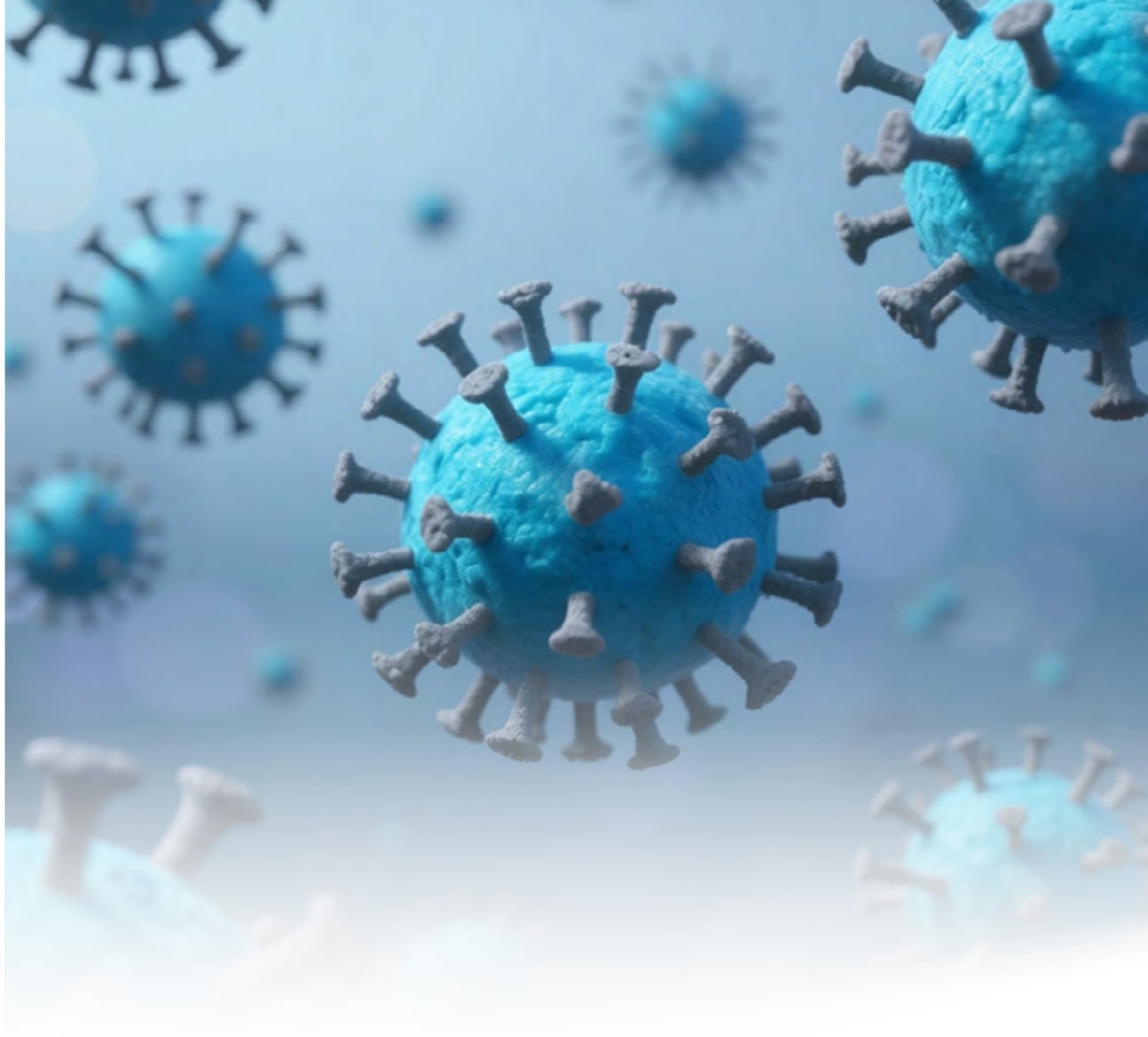
Currently, SERION Immunologics has the capacity to produce antigens such as VZV, CMV or Toxoplasma in a multigramscale. The antigen production facilities are certified up to biosafety level 3 (BSL3) and are EN ISO 13485 controlled, ensuring highest quality standards. This ensures that industrial requirements can be met at any time. The product portfolio includes antigens isolated from pathogen cultivation, e.g. Measles, Mumps, *B. pertussis* (native antigens), or recombinant antigens (e.g. Rubella, VZV), altogether covering a range of more than 80 individual antigens that are produced on a routine basis. All antigens are purified using a range of techniques to ensure optimal performance in diagnostic applications. These include extraction, ultra-centrifugation, filtration and different types of state of the art chromatography processes.

Native antigens are known for their high sensitivity in diagnostic applications, particularly in IgM detection. Recombinant antigens, on the other hand, are well known for their specificity, especially in IgG assays. SERION antigens cover a broad range of infectious diseases including viral, bacterial, fungal and parasitic diseases such as toxoplasmosis and are an ideal basis for the development and production of infectious disease kits and reagents.

Features and benefits:

- ✓ Large selection of antigens
- ✓ Scale up production
- ✓ EN ISO 13485 quality management system
- ✓ Biosafety level 3 (BSL3) production
- ✓ Highest flexibility in customized antigen projects

All antigens are verified to be pathogen-inactivated and certified as non-infectious.
They are routinely packaged in units of 1 mg. 5 mg and 10 mg packaging sizes are also available.
Upon request, bulk quantities can be filled individually.



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SERION plasma

Human sera and plasma are essential reagents in serological diagnostic tests. Infectious disease state plasma/sera are used as manufacturing standards, positive and negative controls or calibrators in most diagnostic test systems. SERION Immunologics offers numerous disease state sera, which are collected in accordance to applicable ethical guidelines.

Plasma is collected from individual donors within a large collection network. Based on continuous routine screening capacities, SERION Immunologics ensures constant plasma availability even of rare disease state sera.

All plasma samples are obtained from qualified and registered donors at approved blood centers in the U.S. or Europe. All samples are tested and certified to comply with regulatory requirements (e.g. donor traceability through the blood bank, virus testing, etc.). The samples are offered as plasma or converted plasma (serum) depending on the customer's needs. The conversion of plasma into serum is performed by a well-established conversion process (re-calcification) to optimize stability and performance of the plasma materials.

SERION Immunologics routinely performs screenings on several parameters for specific antibody positive as well as single or multiple negative plasma/sera.

Please contact us to check current availability or if you are explicitly interested in further items.

Features and benefits:

- ✓ Bulk quantities
- ✓ Broad portfolio
- ✓ Improved stability by plasma conversion
- ✓ Fast screening capacities

Tested negative for:

- ✓ Antibodies against HIV-1 or -2
- ✓ Antibodies against Hepatitis C
- ✓ Antibodies against Syphilis
- ✓ Hepatitis B antigens
- ✓ Nucleic acid test for Hepatits C
- ✓ Nucleic acid test for HIV 1 genome

Notice:
Our SERION plasma products are not clinical samples accompanied with the corresponding clinical data. All serum/plasma offered by SERION Immunologics are usually single-donor bulk samples which are used for the preparation of controls or calibrators. For more information on the availability of human specimen samples, please refer to: www.centralbiohub.com | www.inventdiagnostica.de | www.biomex.de.



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SERION antibodies

As a highly reliable and readily available alternative to human serum, SERION Immunologics also offers humanized monoclonal antibodies.

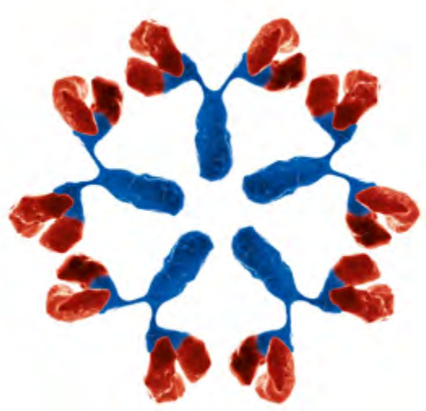


Figure 1:
Mouse constant and variable regions of heavy and light chain
Human region of heavy chain

These monoclonal antibodies have been extensively tested for performance in comparison to human disease state sera, showing that the antibodies behave similarly to sera. Therefore, they can be optimally and alternatively used for preparation of calibrators, controls and standards.

SERION antibodies are produced in transgenic mice by replacing the mouse sequence of the heavy chain constant region (IgM locus) with the corresponding human sequence. After immunization with the antigen of interest, generated antibody clones are cultivated by standard hybridoma techniques. These consist of the human constant region of the heavy chain, mouse variable region of the heavy chain and mouse light chain. The human constant region of the heavy chain can be directly recognized by the anti-human conjugate, which is used in numerous *in-vitro* diagnostic assays. The production process is carried out in collaboration with with Bcell Design (Illkirch-Graffenstaden, France).

The monoclonal antibodies are offered in two different matrices. The original product line is provided as a cell culture supernatant packaged in quantities ranging from 1 mL to 1 L quantities. The new generation of antibodies is available in IgG-depleted and delipidized human serum matrix with 100 µg up to 25 mg packaging sizes. Production lots are usually offered with a concentration range between 100 µg/mL and 150 µg/mL.

Features and benefits:

- ✓ High affinity
- ✓ High specificity
- ✓ Industrial batch sizes
- ✓ Stable, permanent availability
- ✓ Constant quality and performance

A cooperation with:

Bcell Design





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SERION beads

Superparamagnetic microspheres for use in automated bead assays.

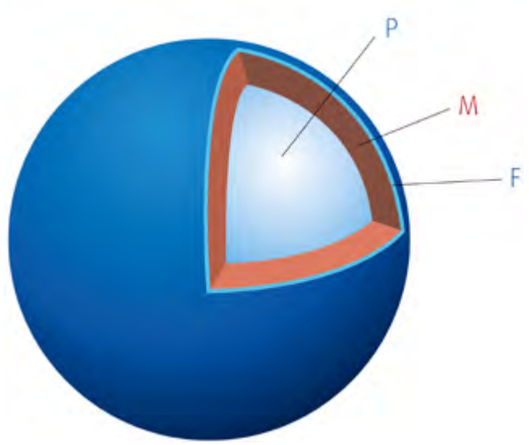


Figure 2:
P = Polymer core
M = Magnetic layer
F = Functional polymer

The new product line SERION beads was developed for automated bead assays, e.g. CLIA. We offer two different kinds of functionalized magnetic beads – MagSERION carboxy beads and MagSERION amine beads. Their small size of approximately 3 µm provides a large surface area for biomolecule coupling and their superparamagnetic properties allow a fast magnetic separation. SERION beads can be activated using standard coupling methods for carboxy or amine surfaces.



Features and benefits:

- ✓ Functional surface groups
- ✓ Fast magnetic separation
- ✓ Large surface area
- ✓ Suitable for automation

Rheumatoid Factor Absorbent Bulk

Efficient removal of Rheumatoid Factor (RF) from serum and plasma samples prior to pathogen-specific IgM detection.

RFs are predominantly anti-IgG-directed IgM-class autoantibodies that can be detected in the serum of patients with autoimmune diseases and approximately 5% of healthy individuals. These IgM RFs preferably bind to IgG immune complexes. Therefore, false-positive results may appear during pathogen-specific IgM detection. In samples with a high concentration of pathogen-specific IgG antibodies, weakly binding IgM antibodies may be displaced by stronger binding IgG antibodies. In such cases, IgM detection without RF absorption can lead to false-negative results. Therefore, it is recommended to pretreat serum samples with RF Absorbent before the detection of pathogen-specific IgM. SERION Immunologics RF Absorbent Bulk contains goat antibodies specifically directed against the Fc part of human IgG. Thus, the RF Absorbent precipitates human IgG together with potentially attached rheumatoid factors without cross-reactivity to other immunoglobulin isotypes. It is specified by a titer of minimum 15 mg/mL and can usually be diluted 3 to 4-fold to the final application concentration.

Features and benefits:

- ✓ High affinity
- ✓ High specificity
- ✓ Industrial batch sizes
- ✓ Constant availability
- ✓ Stable quality and performance



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Bovine Serum Albumin

Variety of BSA products especially selected to cover the needs of the diagnostic industry.

Bovine serum albumin is a globular serum protein of approx. 66.5 kDa. Due to its high stability and its lack of interference in many biological reactions, BSA is widely used in diagnostics test systems. Typical applications include the use as protein calibrator, stabilizer or as blocking reagent.

BSA is often referred to as „Fraction V", based on the original fractionation of human plasma developed by Edwin Cohn. Primarily developed for human albumin production, the process was later adapted to bovine serum albumin. In modern manufacturing processes, Cohn fractionation has now been replaced by a modified, more effective heat shock method, resulting in a BSA with a significantly higher degree of purity (>98 %).

All bovine products are sourced from controlled abattoirs and are manufactured in the U.S. All animals undergo ante- and post-mortem inspections to meet regulatory requirements and are classified as "free from infectious diseases and parasites."

Features and benefits:

- ✓ High stability
- ✓ High purity (>98%)
- ✓ Sourced from controlled abattoirs
- ✓ Manufactured in the US
- ✓ Free from infectious disease and parasites





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SERION customized

SERION Immunologics offers a range of customized services including antigen development and production, manufacturing of coated ELISA plates as well as buffer preparation and lyophilization. If you have any project in mind, please contact us to discuss its feasibility and the best possible production procedure.

Antigens and antibodies:

Due to Virion\Serion's long-term experience as a developer and manufacturer of high-performing, recognized IVD infectious disease antigens, SERION Immunologics is capable of developing and manufacturing a wide range of antigens. Based on the additional expertise of our cooperation partner Bcell Design (Illkirch-Graffenstaden, France), we are also the right partner for the development of new monoclonal antibodies.

ELISA plate coating:

SERION Immunologics offers a fully automated production line for ELISA coating, incubation and vacuum packaging. A modular system enables processing of up to four different lots with individual requirements in one production flow. Embedded in an EN ISO 13485 certified production environment, the state-of-the-art coating system is ready for your batch production.

Buffer production:

SERION customized also comprises the production of tailor-made reagents or buffer formulations, beginning from a simple bottling up to the production of complex buffer solutions. Based on Virion\Serion's certification for the production of *in-vitro* diagnostics according to EN ISO 13485, all products are manufactured to the highest standards.

Lyophilization:

Freeze drying often significantly increases the shelf -life of sensitive biological substances, such as antigens or antibodies. Therefore, this method is widely used in the manufacture of diagnostic reagents and components, such as CFT reagents or conjugates. Lyophilized products can be easily reconstituted with water or a suitable buffer and the reagent can be instantly used in a diagnostic test. Therefore, lyophilization is often the method of choice when preserving sensitive biological substances for long-term storage or to remove the need for shipping of cooled or frozen reagents. Currently batch sizes of up to several thousand vials per lyophilization run can be freeze-dried under continuous quality conditions according to EN ISO 13485.

Features and benefits – SERION customized

- ✓ Maximum flexibility
- ✓ Proven track record
- ✓ Technical customer support
- ✓ EN ISO 13485 quality management system



Contact

For more information about our products and services, please write to us at **immunologics@virion-serion.de** or contact one of our colleagues directly. We are looking foward to your message!

Stefan Papadileris
International Sales Manager

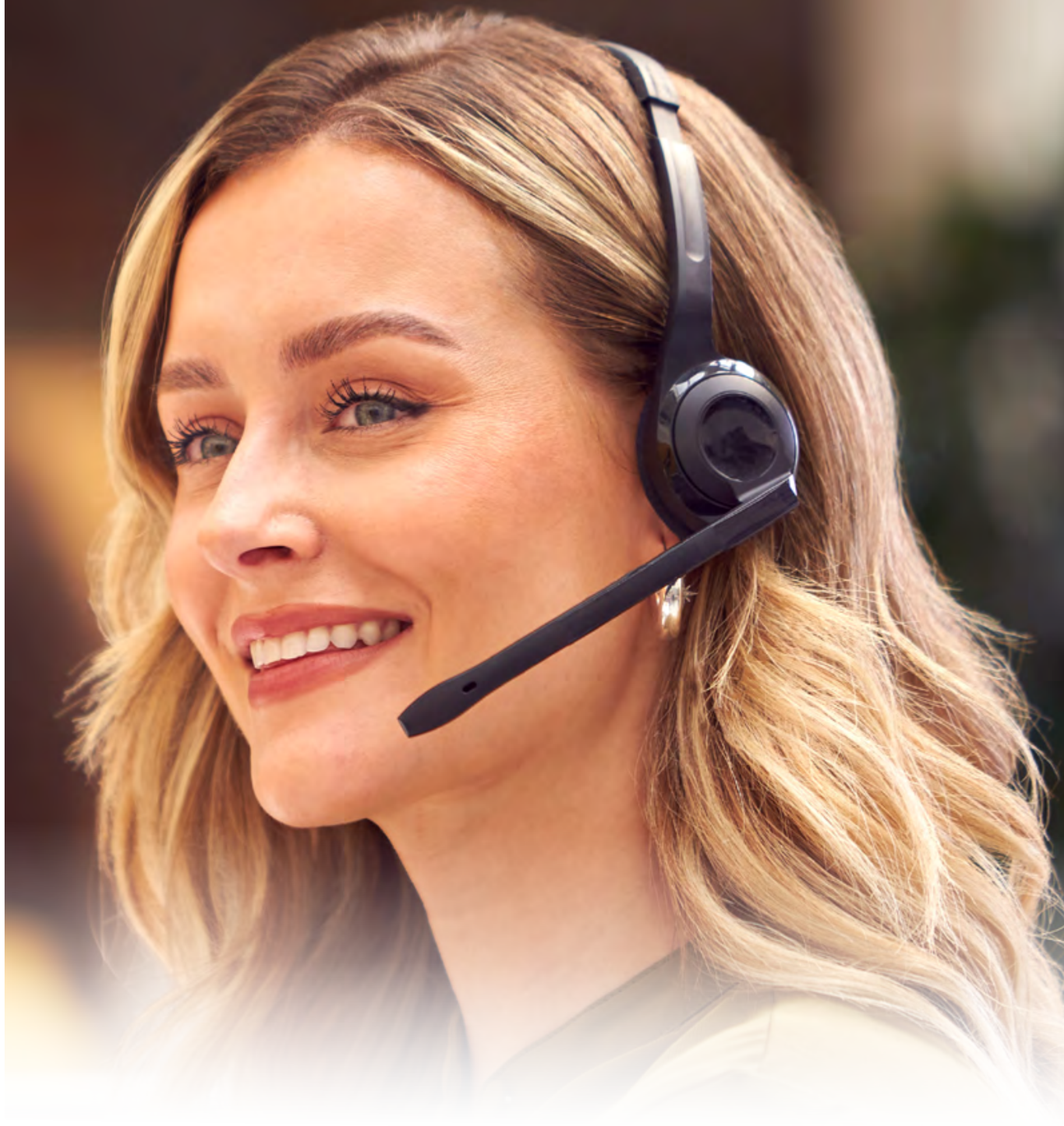
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Notes

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